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with Abnormal Mammography Results

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13. ABSTRACT (Maximum 200 Words) The proportion of mammograms interpreted as abnormal in large screening programs is as high as 15-20%. Thus, if 15% of the 48 million American women 40 years of age or older have mammograms, there would be more than 7 million abnormal mammography results each year. It has been estimated that 30% or more of women with abnormal mammograms fail to comply with follow-up recommendations. This proportion is disparate across racial groups, such that women from minority populations are less likely to receive follow-up than white women. There is little known about why this disparity exists and a need to find out more in order to decrease the number of black women dying from this disease. This study proposed to look at this existing problem from a new perspective—that of the African American woman. The goal of this study was to improve the rates of follow-up in African American women after an abnormal mammogram result by understanding the variables that predict follow-up and developing an innovative intervention through community input that overcomes obstacles to follow-up. Thirty-nine women were interviewed about their health practices, particularly their knowledge, attitudes, and practices associated with mammogram screening. Findings indicate that most of the women are receiving regular care and are fairly positive about the importance of early detection.						
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I. Introduction

Although a higher proportion of black women than white women of all ages have reported being screened for breast cancer, mortality rates for black women are higher than those for white women. Even though the proportion of black and white women with invasive disease upon diagnosis is similar, African American women are more likely to die from the disease. Differences in follow-up and treatment are two of many reasons for this disparity. The proportion of mammograms interpreted as abnormal in large screening programs is as high as 15-20%. Thus, if 15% of the 48 million American women 40 years of age or older have mammograms, there would be more than 7 million abnormal mammography results each year. It has been estimated that 30% or more of women with abnormal mammograms fail to comply with follow-up recommendations. It is also the case that many minority women who obtain one mammogram are also more likely than white women to not obtain re-screening as recommended. This proportion is disparate across racial groups, such that women from minority populations are less likely to receive follow-up than white women. There is little known about why this disparity exists and a need to find out more in order to decrease the number of black women dying from this disease. This study proposes to look at this existing problem from a new perspective-- that of the minority woman. The goal of this study is to improve the rates of follow-up in minority women after an abnormal mammogram result and to improve re-screening rates by understanding the variables that predict follow-up and developing an innovative intervention through community input that overcomes obstacles to follow-up.

II. Overview of Study Findings

During the period of December 1, 2001 thru December 31, 2003, the following accomplishments were achieved:

- Complete literature review of relevant topics (*Appendix A*);
- Submission, revisions and approval of final study protocol (*Appendix B*);
- Submissions and completion of Human Subjects Research Review Board (HSRRB) approval (*Appendix C*)
- Submission of Local Internal Review Board (IRB) package (*Appendix D*);
- Approval of Local IRB (*Appendix E*);
- Development of materials to educate state health department and obtain their consent to proceed (*Appendix F*);

- Development of study interview guide (*Appendix G*);
- Agreement from three Local Health Departments (LHD) to participate in the study;
- Local site visits to each LHD to provide training and furnish materials for conducting study;
- Ongoing monitoring of LHD activity and technical assistance when problems needed to be addressed;
- Collection of interview data from participating women; and,
- Data entry and analysis for final report writing.

An annual report of these accomplishments was submitted in February 2003 and later approved without revisions. This final report provides the analysis of the data collected for this project, including the key research accomplishments and study conclusions.

a. Study Overview

As indicated in the description of the study (*Appendix F*), all participants in the study had at one time been screened for breast cancer through their local health department (LHD), with funding provided by North Carolina's Breast and Cervical Cancer Early Detection Program (NCBCCEDP). This Program is a federally funded initiative, administered by the Centers for Disease Control and Prevention (CDC), that provides breast and cervical cancer screening and diagnostic services to women at or below the poverty level (CDC, 2003). CDC requires that 75% of the women screened in each of the funded programs be 50 years of age or older. By working with the North Carolina Department of Health and Human Services (NCDHHS) to collaborate on this study, and recruiting women through LHDs located in low-income and/or racially diverse areas of the state, this study was ensured a sample of women at relatively high risk for breast cancer.

Through the method described in detail in the approved study protocol (*Appendix B*), women were invited to participate in a face-to-face or telephone interview to discuss their overall health care issues, particularly related to breast health (see *Appendix G for interview guide*).

Methods

Obtaining a working partnership with State Health Department (SHD) staff for this study proved to be a challenge in the implementation of this study. Even

though the Principal Investigator (PI) has a long-standing and positive relationship with the SHD, an extensive review and approval process was followed before this study was allowed to proceed. Materials in *Appendix F* were developed to provide an overview of the study in March 2002 and was shared with management in obtaining approval. Upon approval in May 2002, several meetings were held with the North Carolina Breast and Cervical Early Detection Program and the PI for this study. For each meeting, we reviewed the process for data collection and developed a strategy that was suitable to the SHD and HSRRB. It was then left to the SHD to use the criteria for inclusion in the study and select 3-4 local health departments that would be asked to participate. Criteria for selection included that they had screened a higher than average number of minority women and had numerous cases that had either failed to follow-up for abnormal results or for re-screening as recommended. In June, the SHD staff selected 4 counties to participate and visited each county in person to explain the study and ensure their willingness to participate prior to the PI meeting with each department. Ultimately, three of the four LHDs agreed to participate in the study. These included the LHDs located in Cabarrus, Randolph, and Robeson counties.

Each of these counties was selected for a variety of reasons. Primary selection criteria included that the counties included a diverse population so that there would be a high proportion of minority women being screened by the LHD. Criteria also included that the LHD had a high number of women on average they are required by NCBCCEDP to screen in order to ensure a somewhat large proportion of women with varied follow-up behaviors. It was also critical that the LHD had shown difficulty in obtaining re-screenings, such that at least half of the women screened in their local Program were not returning annually for mammograms. It was also hoped that counties in different regions of the state could be selected as well as those LHDs that had stable staff who were willing to work on this type of project. Each LHD received compensation of \$1000 for providing staff time to assist in recruitment for this study. Table 1 provides some summary data on the selection criteria used in identifying each of these counties.

Table 1.
Summary Statistics on Selection Criteria for Each Participating County*

County (Region)	Number Contracted to Screen ¹	Number Screened in 2002 ²	Re-screening rate ³	Number who have not returned in past 18 months ⁴
Cabarrus (southwest)	394	281	49%	78
Randolph (central)	196	130	50%	52
Robeson (southeast)	181	152	49%	64

¹ Number of women LHD has contracted with NCBCCEDP to provide breast screening for in a given fiscal year.

² Number of women reported by LHD as receiving screening mammogram in Fiscal Year (FY) 2002 (July 2001- June 2002).

³ Average rate of women 50 years or older who return for annual mammograms at LHD.

⁴ Number of women receiving a screening mammogram within the past 3 years but have not returned for a re-screening in the past 18 months (and are therefore over 6 months due for a re-screening).

Prior to the local visits by the PI, the NCBCCEDP met with each LHD to describe the study and provide them with a computer printout of the women (with coded identifiers) who met the criteria for the study. These criteria included women meeting one of two criteria:

- a mammogram obtained at least 2 of the past 3 years (during FY 1999-2001) as recommended for her age group; and,
- no mammogram obtained for all 3 years or no diagnostic care for those who received an abnormal mammogram result.

The plan was that this printout would be utilized by the LHD staff to identify the women to invite for participate in the study.

Once the NCBCCEDP staff met with the LHD, the PI then met with each LHD. During the local visits, each LHD was provided 60 self-addressed, stamped envelopes to mail to qualifying women (*Appendix F*). The envelopes included a letter from the LHD (on their letterhead) that explained the study, copies of the consent forms, and an envelope addressed to the PI. The women were instructed to sign a consent form, provide their contact information, and return the forms in the stamped envelope. Each LHD distributed all of their packages to women for a total of 180 invitations to participate. However, each LHD relied on

their own list of women meeting the criteria (from notecards maintained by the clinic manager), instead of the printout supplied by the NCBCCEDP. Utilizing the printout would have required the LHD staff to decipher the identifiers for each woman, pull her medical chart, and obtain her contact information. However, using the notecards allowed the LHD to just pull each card of women who had not been receiving regular mammograms.

A total of 44 signed consent forms were received by the PI (24.4%). One of these forms was incomplete and did not provide sufficient contact information from the woman to identify her and follow-up. Another four of the women returning the completed forms were contacted at least five times by an interviewer but never replied to scheduling an interview. In total, 39 (88.6% (or 21.7% of total)) women completed an interview. Because of the limited amount of time left to conduct the study and collect the data prior to expiration of local IRB approval, the majority of interviews were conducted over the phone. Face-to-face interviews required significant travel so time seemed best utilized by conducting more interviews over the phone. A total of 5 face-to-face interviews were conducted in the woman's home, while the remaining 34 (87.2%) interviews were conducted via the telephone. A \$50 compensation was provided to all women who completed an interview.

Analysis

Each interview was audio recorded and notes taken by the interviewer throughout the discussion with each woman. The taped interviews were then transcribed into Word documents and later used to create a data set in Excel. Codes were assigned to quantitative, close-ended responses to questions for data entry and analysis. Quantitative data that are presented include frequencies, means, and simple statistics as derived through Excel. For the qualitative data analysis of open-ended interview questions, responses were coded to identify the theme for each question, using color coding and standard qualitative data analysis methods (Miles & Huberman, 1994). A count of the women responding for each theme is provided with verbatim quotes presented throughout this report. In many cases, these counts are greater than the total number of women in the study since respondents sometimes provided more than one response to a question. Each response provided was coded separately and captured in the data analysis.

b. Overview of Study Results

Sample Characteristics

Study participants ranged in age from 51- 68 years, with a median of 56 and a mean of 59.5 years. More than half of the participants were African American (24: 61.6%), while 8 (20.5%) were White and 7 (17.9%) were Native American. Nearly half of the women (46.1%) did not complete high school, with the mean years of education of 11.3. Table 2 provides a summary of key demographic information for the study sample.

**Table 2.
Demographic Characteristics of the Sample**

Characteristics	Number	%
Age (years)		
50-55	6	15.4
56-60	17	43.6
61-65	10	25.6
> 65	6	15.4
Race		
African American	24	61.6
White	8	20.5
Native American	7	17.9
Education (years)		
< 10	10	25.6
10-11	8	20.5
12 or GED	12	30.8
> 12	9	23.1
Employment		
Retired	7	17.9
Employed	17	43.6
Unemployed/Homemaker	9	23.1
Disabled	6	15.4
Marital Status		
Married	12	30.8
Widowed	6	15.4
Separated/Divorced/Single	21	53.8

The focus of the interview asked women about their health behaviors, particularly those related to breast health. The following sections provide a summary of the data for each of the major categories of questions, including their overall health care behavior, history of receiving breast health exams, as well as mammograms, and their knowledge and attitudes to seeking breast health care.

Overall Health Care Behavior

In assessing their overall health care practices, a series of questions were asked about whether they have a regular doctor or nurse, how recently they received breast health care, among others (*Appendix G, Section I*). The following provides a summary of key findings.

Most of the women (35: 89.7%) indicated that they do see a doctor or nurse on a regular basis. Over three-fourths (31: 79.5%) had seen a doctor or nurse for breast health care within the past year. The remaining eight (20.5%) reported a visit to a doctor or nurse for breast health within the past 1-2 years. The most common reason for their last visit to a doctor or nurse was for an annual check-up or physical (34: 87.2%), while the remaining 5 (12.8%) went for a visit to obtain follow-up care or to be examined for current problems such as a lump in their breast they had palpated.

Experience with their Local Health Department

Of key interest to the NCDHHS was the level of satisfaction among women about their encounter at their LHD and reported reasons that they may not return for care. Questions related to this were added into the interview guide in order to provide feedback both to the State and Local Health Departments. These questions focused on the women's reasons for obtaining care at the LHD, whether they had returned for care, their level of satisfaction they reported during their visit, among other factors (*Appendix G, Section I*).

Overall, women reported being very satisfied with the breast health care they had received through their local BCCEDP program. Women were asked to rate their level of satisfaction with this care on a 3-point scale, from 'very satisfied' (scored as a 1) to 'not at all satisfied' (scored as a 3). Nearly all of the women reported being very satisfied with their care, while 5 (12.8%) stated they were somewhat satisfied, for a mean of 1.1. The reason reported by the most women for being so pleased with the care they received was that the care was thorough and the

nurse explained things well (19: 48.7%). The following provides quotes from the women's responses:

"...they explained things very well..."

"...she did a good job and examined me and answered all the questions I had..."

"...they were very careful with me and just took very much interest in me".

Another primary reason for the high level of satisfaction was that the women felt they had been treated with respect and courtesy (11: 28.2%). One woman even stated that the LHD is the only place she can go where she can count on "*...being treated like a person not like a number*". The following quotes provide some details of these related responses:

"...treated me with respect...courtesy...explained everything to me..."

"...they were just nice and professional..."

Women reported initially obtaining services from the LHD for a variety of reasons (*Appendix G, Section I, Item 9*). Ten of the women (25.6%) reported that they had obtained their mammogram at the LHD for financial reasons—because that was the only way they could afford it. Ten women (25.6%) reported that they had obtained a mammogram because their doctor had recommended that they go to the LHD for this service, and eight women (20.5%) indicated that their age was their reason for getting a mammogram. Seven women (17.9%) indicated that another reason to obtain their mammogram was to 'be sure I'm OK' or because they were due for one. Fewer women reported current breast health problems (2: 5.1%) or family history (1: 2.6%) as their reasons for obtaining a mammogram. Table 3 provides a summary of the findings for this item.

Table 3.
Reasons for Obtaining Mammogram at LHD

Reasons for Obtaining Mammogram at LHD	#	%*
Financial reasons (i.e., no insurance, low income, etc.)	10	25.6
Provider recommended it	10	25.6
At risk due to age	8	20.5
To 'be sure ok' or 'it was time'	7	17.9
Current breast problems (cyst, pain)	2	5.1
At risk due to family history	1	2.6
Don't know	1	2.6
Total	39	100.0

*Percentages are rounded to the nearest tenth and may not total 100%.

Women were also asked how they came to know about obtaining breast health services at the LHD. Respondents provided a variety of answers to this question. Advertisements through posters, letters, and in newspapers, were reported by 13 (33.3%) women as how they initially learned of these services. Referrals within the community also seemed to be an effective mechanism for outreach to qualifying women, with 10 (25.6%) reporting being referred by another clinic (either one within the LHD or at another local agency), 3 (7.7%) referred by attending a local community event, such as a workshop on breast health, and 2 (5.1%) referred by their private physician. Word of mouth was also responsible for 5 (12.8%) women hearing about the program through family members or friends.

When asked a more specific question about the Program, asking whether they had ever heard of the 'Breast and Cervical Cancer Early Detection Program' (*Appendix G, Section I, Item 10*), over half (53.8%) reported that they had not heard of this Program. Those women who reported hearing about that Program reported learning of it through other local clinics (9: 25%); the newspaper (3: 7.7%); or one each of their local providers, a community class they had attended, a friend told them about it, or they had been to the LHD before and knew about it. Most of the women (71.8%) reported that none of their family members or close friends were receiving services through this Program.

Women in this sample had obtained care from their LHD within the past three calendar years, but had not necessarily returned for care at the LHD since their initial visit. They were therefore asked two questions about whether they had

returned and if not, what were their primary reasons for not returning (*Appendix G, Section I, Items 4-5*). First, women were asked to indicate where they had received care during their last breast health visit. Twenty-one (53.8%) reported their last visit was at the LHD. Another 11 (28.2%) reported receiving this care through a local private practice; while 7 (17.9%) obtained care at a hospital setting.

Second, respondents were asked when was the last time they went to the LHD for their breast health care. Six of the women (15.3%) had not returned to the LHD: five because they now have private health insurance and no longer financially qualify and one because she stated she has another medical bill to pay and cannot afford to get a mammogram. The remaining women had returned to the LHD within the past year (21: 53.8%); 1-2 years ago (7: 18%); or could not recall when they had last been to the LHD.

Breast Health History and Care

Women were asked a series of questions about when they had last obtained a clinical breast exam (CBE) and mammogram, as well as whether they had ever been diagnosed with breast problems (*Appendix G, Section II-III*). Almost all of the women had received a CBE within the past 2 years (33: 84.6%), with only 1 (2.6%) reporting that she had never received one and 5 (12.8%) indicating it had been more than 2 years since their last one. Table 4 provides a summary of the findings for reported breast health care.

Table 4.
Summary of Breast Health Care

Characteristics	Number	%
Clinical Breast Examination History		
Never	1	2.6
Within past 2 years	33	84.6
More than 2 years ago	5	12.8
Mammogram Utilization		
Within the past year	32	82.1
1-2 years ago	5	12.8
2+ years ago	2	5.1
Results of Last Mammogram		
Negative	33	84.6
Follow-up Complete/Negative Findings	3	7.7
Follow-up Ongoing	3	7.7
History of Breast Problems		
Yes	13	33.3
No	26	66.7

Mammogram Utilization

In terms of mammogram use, all but 7 (17.9%) had received a mammogram within the past year. Of the 32 (82.1%) women reporting receiving annual mammograms, all of them indicated that they obtain them annually or sometimes every six months, depending on their family history or other risk factors, such as age. Fourteen (35.9%) obtained mammograms regularly because they wanted to 'make sure everything is ok' and that they 'don't have cancer'. Another common reason given for obtaining regular mammograms is that the health department or doctor 'told me to' (5: 12.8%).

Of the seven not receiving a mammogram in the past year, five had received one within the past 2 years and the remaining two had received a mammogram more than 2 years before. Reasons given for not receiving mammograms annually included two women reporting they were 'just lazy' and had not made an appointment; two women reported that it was difficult for them to get off work for an appointment; two had been sick quite a bit during the past year and unable to

attend; and the remaining woman stated that she just had to 'pay so much' for a mammogram she couldn't afford it. All of these women reported that they had been encouraged by their provider to obtain annual mammograms and they plan to do so in the next 6-12 months.

Results of Last Mammogram

Twenty-eight (71.8%) of the women had received their last mammogram through the local BCCEPD program, while 11 (28.2%) had received theirs through the office of a local doctor or nurse. The majority of results from their last mammogram were negative (33: 84.6%). However, two had learned they had cysts, three were scheduled for repeat mammograms, and the remaining woman had completed follow-up and received negative findings.

History of Breast Problems

Thirteen (33.3%) reported that they had been diagnosed with breast problems, such as a lump or cyst, with two of these indicating they had been positively diagnosed with breast cancer in prior years. Of the remaining 11 with prior breast problems, 10 (25.6%) were told they had benign findings (i.e., cysts, dense breast, etc.), while the remaining one was still being followed for additional testing.

Barriers to Mammogram Screening

Women were asked about barriers they had experienced in getting a mammogram on a regular or yearly basis. Many of the women who were obtaining annual mammograms (19: 48.7%) reported no barriers to receiving this care. The remaining thirteen women reported cost as a barrier (9: 23.1%); pain of the procedure itself (3: 7.7%); or, one who reported that sometimes she's not sure if she would want to know that she has cancer.

Social Support for Regular Breast Health

Studies have indicated the importance of social support in encouraging women to obtain regular mammograms (Danigelis, Roberson, Worden, Flynn, Dorwaldt, Ashley, Skelly, & Mickey, 1995). Women in this study were asked a series of questions about the extent to which their family and friends encouraged or discouraged regular breast health care (*Appendix G, Section IV, Items 9-10*). Overall, women indicated that both their family and friends are supportive of them

receiving regular care. Only two women indicated that their family is not supportive of receiving this care and their open-ended responses indicated that they just don't discuss this health care with their family members. Several women (11: 28.2%) indicated that their children are the ones most likely to encourage them to obtain screening. Women were also asked to indicate how many (all, almost all, a few, or none) of their closest friends obtain regular mammograms. This item was coded on a scale of '1' ('all') to '4' ('none'). Most of the women indicated that 'almost all' (11: 28.2%) or 'a few' (16: 41.1%) obtain regular mammograms, for a mean of 2.3 (Table 5).

Table 5.
Closest Friends Obtaining Regular Mammograms

Risk Factors	Number	%
All	8	20.5
Almost all	11	28.2
A few	16	41.1
None	2	5.1
Don't know	2	5.1
Total	39	100.0

Overall, women indicated that their friends were supportive of their screening behavior and encouraged or reminded them to go.

Breast Health Knowledge and Attitudes

Respondents were asked a series of questions about their knowledge and attitudes related to breast health care, including how often they think they need to get a mammogram, risk factors of breast cancer, among others (*Appendix G: Section IV*).

Knowledge of Breast Health

Women were asked a series of questions about their knowledge of mammogram screening or what would happen if they were diagnosed with cancer. Since fear of diagnosis has been shown as a barrier to obtaining regular screenings in other studies (Tessaro, Eng, & Smith, 1994), questions about these topics were asked of women to better understand how to address this fear.

First, women were asked about when to obtain mammograms and whether women 50 years or older should receive annual tests. All but two of the women indicated that they think women should receive mammograms at least annually, with some of these stating that every six months would be how often women should obtain this test. The two women who did not indicate this thought that screening every 18-24 months is sufficient. These two women also disagreed that women 50 years or older should 'get mammograms every year', while the remaining 37 (94.9%) indicated that they agree with this statement.

Second, women were asked a series of four questions about what 'cancer' meant to them and what would happen if diagnosed with breast cancer. The responses to the question "what does the word 'cancer' mean to you" were very interesting. All of the women provided rather strong statements of fear about cancer. Eighteen women (46.1%) in particular noted that cancer is very scary to them, frightening, and invokes fear when they hear the word.

"...frightens you to death..."

"it's a scary word to me...I see people with it and what it does to them..."

"...horrible...horrible...just horrible...I hate to hear the word really"

"oh lordy, when you hear the word you just shake your head"

In addition, nearly half of the women (18: 46.1%) equated the word cancer with death, as evidenced by the following quotes.

"...death...hopelessness...something uncontrollable...it's a horrible way of dying"

"...death...it's a lot of pain...I think if I got cancer then I would just die"

"..death...that it's an illness there is no cure for..."

Only six (15.4%) women indicated a response with some understanding of the disease itself and that early detection can help to alleviate the risk of death.

“...to me that’s a real bad disease but if it’s caught in time I think you can overcome”

“...it’s a very important disease that you need to stay on top of..”

“...it’s a fear, a fear for your health whether it’s caught in time or not”

When asked about the types of treatment a woman would have to undergo if diagnosed with breast cancer, most women (24: 61.5%) indicated an understanding that there are a variety of treatments available and diagnosis of cancer would not necessarily mean a woman had to have a mastectomy. Some women indicated that they don’t know (7:17.9%) what a woman would encounter, and two indicated that they thought she’d have to definitely have her breasts removed. Two women were fairly inaccurate in their knowledge about treatment with both indicating that a woman diagnosed with breast cancer would have to start exercising and go on a diet. One woman’s response was intriguing in that she said that a woman diagnosed would have a lot of choices but she’d die anyway:

“oh lord...so much...and she’d end up dying anyway”

When asked about whether a woman diagnosed with breast cancer will survive and live a good life for at least 10 more years, most women (29: 74.4%) thought that the chances were ‘very good’ or ‘likely’ that she would survive. Most of these women also indicated that her chances would be even better if the cancer was diagnosed early. Only a few women indicated that they don’t know what the chances of survival would be (3: 7.7%) or that a woman’s survival was not very likely (4: 10.2%):

“not likely...just gloom and doom about breast cancer”

“...probably like a 1 out of 5 chance [of surviving]”

Women were also asked about their risk of cancer in terms of ‘what do you think makes a woman your age more likely to have breast cancer’. There was a vast array of responses to this question as shown in Table 6. Fifteen (38.5%) women thought the risk was due to heredity, while eleven (28.2%) indicated it was because of age or just getting older. Ten women (25.6%) indicated they don’t

know but the remaining women gave a variety of possible risk factors that are not necessarily supported by the current knowledge of breast cancer.

Table 6.
Stated Risk Factors for Developing Breast Cancer

Risk Factors	Number*	%
Heredity	15	38.5
Age	11	28.2
Diet	5	12.8
Don't take care of yourself	4	10.2
Smoking	3	7.7
Taking birth control/hormones	2	5.1
Injury to the breasts	2	5.1
Overweight/not active	2	5.1
No children or age when had first child	2	5.1
Menopause	1	2.6
Just something in your body	1	2.6
Stress	1	2.6
Live near a chemical plant	1	2.6
Don't know	10	25.6

*Note: Total is higher than sample size since women could provide more than one response.

Women were also asked whether they know anyone who has ever been diagnosed with breast cancer, how that person is doing, and what impact, if any, that person's cancer has had on their screening behavior. Twenty-eight women (71.8%) indicated that they know someone who has been diagnosed with breast cancer, of these most knew friends or neighbors who were diagnosed, while 8 (20.5%) noted that this person is a family member, such as a sister, aunt, or cousin. Of these women, 24 (61.5%) indicated that knowing someone with breast cancer greatly influenced their screening behavior:

"it scares me when it's that close to home you know..."

"...it influences my way of thinking about getting care...she waited [to get screened and later died from it]...so her experience made me more aware to get screened..."

“...it has [influenced me], to know that if it is caught early there is hope and surgery really can work...”

“yes, they died...very much [it influenced me]...they didn’t have regular screening so I do...”

Attitudes about Breast Health

As previously noted, the majority of women in this study were receiving annual mammograms as recommended for their age group of 50 years or older (ACS, 2003). In general, most therefore had positive attitudes about receiving this care. Women reported that they obtain annual mammograms primarily because they want to know everything is ‘ok’ with their health. Twenty-two women (56.4%) indicated they go for regular mammograms because they want to find out about their health and know they are ok, as evidenced by the following quotes:

“I think it’s a good thing for women to get for their health”.

“...it eases my mind to get it on a regular basis...gives me confidence that everything is ok...”

“lets me know if I had anything abnormal about my breasts”

“...look forward to taking it because I want to make sure I’m taking care of myself...”

In addition to these comments, several women (6: 15.4%) indicated that they understand the value of screening in order to detect cancer early.

“..early detection is the best..”

“...they can detect the cancer in the early stages and they may be able to cure it...”

When asked about the negative aspects of receiving regular mammograms, 14 (35.9%) indicated that it was a painful or uncomfortable procedure. One woman stated that her last mammogram left her with bruises on her breasts and another woman stated that “*they could be more sensitive*” in providing the mammogram, since it made her feel like she was “*treated like meat*”. Overall, most women

were positive about the experience and planned to continue receiving annual re-screenings.

Women were also asked about reasons they may use to postpone getting a mammogram. Several women (12: 30.8%) indicated that there are no reasons for postponing getting a mammogram since it is so important to receive them annually. Reasons for delaying screening included 6 (15.4%) who indicated that they would or have postponed screening because they were sick, 3 (7.7%) each indicated that either not having enough money to pay for the mammogram or being afraid of the results was a reason to postpone getting the test, and two indicated that they would postpone it when thinking about the pain or discomfort of getting a mammogram.

III. Key Research Accomplishments

The following is a summary of the key research accomplishments over the course of this study:

- Thorough literature review of relevant articles to use in the development of the interview guide;
- Approval of both local IRB and HSRRB to proceed with study;
- Conduct of 39 face-to-face or telephone interviews with women of color and low income;
- Analysis of both quantitative and qualitative data for presentation in this final report.;
- Development of an executive summary of the study (*Appendix H*) to share with NC DHHS to collaborate on a possible strategy for improving re-screening and/or follow-up rates.

IV. Reportable Outcomes

The reportable outcome for 2002 included the literature review chart created to guide the development of the study protocol (*Appendix A*). The outcomes for 2003 and the remainder of the study include:

- Completed interviews with 39 participants;
- Completion of all data collection by March 7, 2003 (when local IRB approval expired);
- Data entry and analysis;
- Final study conclusions and recommendations; and,

V. Conclusions

This study required an additional year for completion than was originally planned. Two major barriers were encountered in implementing the study. These barriers included the time required to obtain final approval from both the SHD and HSRRB to proceed with the study. Because of these delays, a no-cost extension was requested in October, 2002, and was obtained in December. This study then concluded on December 31, 2003.

Once the primary barriers were overcome, the study proceeded as planned. All data collection ceased on March 7, 2003, since that was the deadline for local IRB approval. To meet this deadline, interviews were conducted in person when feasible, with the majority conducted over the telephone. A total of 39 interviews were conducted with qualifying women, including mostly African American women (24: 61.6%), of low income, who had received screening from a LHD in the past three years but may have failed to obtain follow-up with diagnostic tests or a re-screening mammogram during that time.

Overall, the findings of this study indicate that the women in this sample are relatively positive about the ongoing need for early detection of breast cancer and seem to understand the value of this behavior. Most of the women (32: 82.1%) had been obtaining mammograms on an annual basis. Of the seven who had not, their primary reasons were that they were too busy and had to work so could not schedule an appointment or that they had been too sick with other illnesses to get a mammogram. All seven expressed intentions to obtain a mammogram within the next six to twelve months.

Implications from this study include three strategies that could be utilized to provide outreach to more women for screening and re-screening and to help promote adequate follow-up care:

- 1. Utilizing breast cancer survivors more in delivering messages of the importance of early detection.** Many women acknowledged that they knew some survivors of cancer, but few were breast cancer survivors. The women also overwhelmingly expressed great fear and anxiety over the potential for a diagnosis of cancer. While much of this fear is real, it could be alleviated by introducing women to those who have survived the disease so that they understand that it is quite likely that, if found, a woman can survive diagnosis, and that cancer does not necessarily mean death, like many women seemed to believe.

- 2. Delivering breast health care messages through the adult children of older women.** Interestingly, several women noted that they are encouraged or reminded by friends and family members to obtain regular screening. In addition, a number of women noted that they get this support from their adult children. A viable strategy would be to provide for education of adult children so that they can promote ongoing screening behavior with their parents. Strategies could be developed to enlist their ongoing support and enhance their understanding of the importance of early detection.
- 3. Increase awareness of the ongoing availability of NCBCCEDP funding and the need to continue receiving services.** Many of the women knew about the NCBCCEDP and knew that this Program (or the LHD) had paid for at least one of their mammograms. However, several also seemed to indicate that they did not know they could continue to access this Program if they were financially eligible. Strategies could be used that would continuously inform women of the availability of this Program, so that they understand they can return for re-screening and receive the same kind of financial support that they did the last time they obtained a mammogram.

In applying these implications, it is important to keep in mind the limitations of this study. In order to obtain both NCDHHS and HSRRB approval, a number of concessions had to be made that impacted the PI's ability to reach the population of greatest interest. It was hoped that this study would reach primarily women of color who had either not obtained follow-up care as recommended or had not returned for re-screening mammograms. As evidenced by this sample, the majority of women included in this study did not meet these criteria. Problems impacting the characteristics of the sample included relying on LHD staff to invite women to the study who met the criteria instead of allowing the PI to review charts and identify women to include in the study. While the LHD staff were willing to participate and it is likely that many women who met the study's criteria did receive invitations to participate in this study, most of these women did not opt to be interviewed.

Another strategy that was planned to increase study participation was a direct invitation to the women, by phone, to explain the study, answer questions, and obtain her consent. The PI had planned to make this initial contact and invite women to participate. However, because of IRB and NCDHHS constraints, the

PI was not allowed to have contact with the woman until she consented to participate. The SHD thought that phone calls to the eligible women by LHD staff were too burdensome. While the NCBCCEDP provided each LHD with a list of women meeting the criteria of the study, each LHD opted to use their own system for identifying women to invite to participate. Ultimately, this initial contact was conducted by mail and proved to be a fairly ineffective way to recruit women into a study of this nature. If this study were to be repeated, considerations should be made that would enhance participation in the study among women who are not receiving adequate screening and/or diagnostic breast health care.

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APPENDIX A

Source	Purpose	Methods	Results
Aziz H, Hussain F, Sohn C, Mediavillo R, Saitta A, Hussain A, Brandy M, Homel P, Rotman M. Early onset of breast carcinoma in African American women with poor prognostic factors. Am J Clin Oncol. 1999 Oct;22(5):436-40.	Determine significance of age and race at onset of BC	Retrospective study 713 patients w/ BC (327 W and 386 AA) other races excluded 2 NY hospitals from 1983 to 1993	Used MV analysis Found that AA women developed BC 10 years earlier than W women.
Tessaro I, Eng E, Smith J. Breast cancer screening in older African-American women: qualitative research findings. Am J Health Promot. 1994 Mar-Apr;8(4):286-92.	To discover why older AA women perceive and react to BC the way they do	Focus groups (14) from various AA social groups and some sons and husbands women	1)BC risk not major concern for AA women over 60. Younger women did consider BC major concern. 2)Age not seen as risk factor but family history was. 3)Believed no difference in risk bn AA and W women 4)believed AA less likely to seek treatment than W Believed BSE and physician exam to be as effective as mammography. 5)Fear may be factor – many practiced BSE but didn't go to Dr. 6)Cost 7) older AA women tend to seek care for specific problem and not for preventive med. 8) Family over self; privacy
REPORTS ON FOLLOW UP OF AB MMG!!!!!!	Describe follow-up behavior for women with seriously abnormal mammograms.	Retrospective chart review 92 women in HMO 90% AA 40% over 40 80% Medicaid 50%+ income < \$20,000	Rate of follow-up within 60 days for seriously abnormal mammograms was 32% Beyond 60 days was another 35% Not completed was 34%
'Skinner CS, Arfken CL, Sykes RK. Knowledge, perceptions, and mammography stage of adoption among older urban women. Am J Prev Med. 1998 Jan;14(1):54-63.	Understand older urban women's attitudes and perceptions about breast cancer by stage of mammography adoption	Telephone interviews by female grad students Sample recruited from peer volunteer program Mean age 72.5 88% AA 32% less than 8 th grade education	Good sample stats... 42% knew early BC not painful 37% knew BC doesn't = mastectomy 59% knew Fam. History = >risk 38% knew risk > w/age <50% knew that physical contact and breast size does not = >risk 18% knew that bumps/bruises don't = BC

			<p>More women were sure that mammogram could find BC early than it's ability to find "before big enough to feel" ...</p> <p>More likely to have mammogram w/in previous 2 years if:</p> <ul style="list-style-type: none"><75, more education, nonsmokers, rcvd reg. med care @ clinic, saw MD 2X in previous year.
Champion VL, Memon U, McQuillen DH, Scott C. Validity of self-reported mammography in low income African American women. <i>Am J Prev Med.</i> 1998 Feb; 14(2):111-7.	Compare self-reported mammography rates and medical records.	Interviewed participants about last mammogram then checked medical records Volunteers from women waiting to receive social services 286 useable participants mean age= 54.7	<p>Of 219 reporting mammogram w/in past year</p> <ul style="list-style-type: none">- only 48.4% verifiable-23.7% verified to be completed 13 to 24 months prior- 15.1% more than 2 years prior
			<p>Focus groups and household surveys using social learning theory and HBM.</p> <ul style="list-style-type: none">- 2 tracts with total of 333 participants- 84% response rate- results based on 281 AA women- face to face interview by AA interviewer- Focus groups (3) 90min led by 2 AA women- 2 criteria for participants low income and limited education
			<p>Collect information to develop strategy for addressing barriers to breast screening in low and moderate-income AA women</p> <p>Danigelis NL, Roberson NL, Worden JK, Flynn BS, Dorwaldt AL, Ashley JA, Skelly JM, Mickey RM. Breast screening by African-American women: insights from a household survey and focus groups. <i>Am J Prev Med.</i> 1995 Sep-Oct; 11(5):311</p>
Danigelis NL, Worden JK, Mickey RM. The importance of age as a context for understanding African-American women's mammography screening behavior. <i>Am J Prev Med.</i> 1995 Sep-Oct; 12(5):358-66.	Examine association of predisposing, reinforcing, and enabling factors for AA women X age groups	Stratified random sample N=648 AA women Ages 40+ divided into 3 age groups (40-49; 60-64; 65+) - Bivariate (X2) Screening X age Factor X age - ageXscreeningXfactor interactions	<p>Survey:</p> <ul style="list-style-type: none">- Gives screening stats and opinion stats- 81% heard of mammogram- 63% knew that woman over 50 should get mmg every year- 87% knew CBE should be done every year- 77% believed screening participation mattered to family members- 46% knew women who rcvd reg. breast screening <p>Focus:</p> <ul style="list-style-type: none">- knowledge of screening guidelines appeared limited (?no #'s)- most generally believed they had little chance of getting BC <p>Interaction w/ screening behavior and income level for 3 factors:</p> <p>Having heard of mammogram, screening mattered to family, and being shown BSE in MD's office increased behaviors but increase in mod. Income sign. > than low income</p>

Hedegaard HB, Davidson AJ, Wright RA. Factors associated with screening mammography in low-income women. Am J Prev Med. 1996 Jan-Feb;12(1):51-6.	Looked at factors associated with screening mammography in public health center	N=10982 (n=3521 screened and 7461 unscreened) - 32% W - 23% AA - 40% H - 4% other - 1% unknown	Native American, Asian, and other less < likely to be screened than W, AA, or H. Women on Medicaid 2X as likely as those w/o
Mandelblatt J, Traxler M, Lakin P, Kanetsky P, Thomas L, Chauhan P, Matseone S, Ramsey E. Breast and cervical cancer screening of poor, elderly, black women: clinical results and implications. Harlem Study Team. Am J Prev Med. 1993 May-Jun;9(3):133-8.	Cross-sectional descriptive study Looked at participation rates when Nurse Practitioner approached women in urban public hospital who are already there for routine visit	491 participants	20.6% refused screening 8.4% claimed recent screening 71% participation
Pearlman DN, Rakowski W, Ehrlich B, Clark MA. Breast cancer screening practices among black, Hispanic, and white women: reassessing differences. Am J Prev Med. 1996 Sep-Oct;12(5):327-37.	Examine differences in screening behavior by race (B,W,H) TTM stages Current screening and intention to have mmg	National Database from NHIS-HPDP N=9219 Ages 40-75 Classified according to TTM stages W=80% of sample AA=15% H=5%	AA and H at >risk of underscreened or unscreened - H in south sign more likely to be underscreened or unscreened - Lack of physician recommendation major barrier?
Wagner TH. The effectiveness of mailed patient reminders on mammography screening: A meta-analysis. Am J Prev Med. 1998; 14(1):64-70.	Meta-analysis: Compare effectiveness of mailed patient reminders at increasing mmg screening	Articles using controlled randomized trials N=16 articles In US=12	Women in US receiving reminders are more likely to get screening Tailored letters associated w/sign > rates of mammography
Weinberg AD, Cooper HP, Lane M, Kripalani S. Screening behaviors and long-term compliance with mammography guidelines in a breast cancer screening program. Am J Prev Med. 1997 Jan-Feb;13(1):29-35	Intervention to increase mmg compliance for all hospital employees (FT and PT who qualified for benefits)	Mean age = 55.8 N=239 49.8% W 29.3% AA 11.7% H 9.2% other	Mean number of days in program = 1287.3 - Those requiring fewer invitations, Who were older, who had at least 1 mmg or CBE by T1 stayed in program longer. - time in program not sign related to fam history, having 1 mmg in past year at T1, or performing monthly BSE at T1 not sign. Related to time in program. Of 67.8% who remained active - Greater % of W remained active (81.5%) H = 67.9%; AA=48.6%; o=54.6%
Merkin SS, Stevenson L, Powe N. Geographic socioeconomic status, race,	Compared AA and W women ages 40+	AT T2: - 89.5% reported having mammogram compared to 65.7% at T1 - Mmg use sign. Related to ethnicity - 53.8% W; 46.4% H; 28.6% AA; 22.7% "o"	Found similar trends for AA and W with similar SES.

and advanced-stage breast cancer in New York City. Am J Public Health. 2002 Jan;92(1):64-70.	On incidence of BC based on cancer registry info from NY	37921 cases	<ul style="list-style-type: none"> - adjusting for age and year at diagnosis – lower income and education increased odds of late stage BC (50% AA and 75% W) - AA presented at younger ages - Area SES associated with race - % of unknown and distant stages decreased steadily as income and education increased <p>Methodological problems!</p> <p>Left out some zipcodes for incomplete info. These were mostly low income areas and low income areas tended to have higher % AA pop. Left out hospital for not reporting race</p>	<p>Increasing age, lower educational attainment and lower income were negatively associated with physician recommendation</p>	
O'Malley MS, Earp JA, Hawley ST, Schell MJ, Mathews HF, Mitchell J. The association of race/ethnicity, socioeconomic status, and physician recommendation for mammography: who gets the message about breast cancer screening? Am J Public Health. 2001 Jan;91(1):49-54.	Investigate association between physician recommendation of mmg and race, SES, and other characteristics	Sample from baseline measure of Program funded by NCI through UNC Specialized Program of Research Excellence in Breast Cancer	<p>Age = 52+ N=1933 45 min questionnaire by trained interviewer self-report of MD recommendation is primary outcome measure</p> <p>Ages 18-64 For mmg ages 35-64</p>	<p>Odds of never having mmg increased as education level decreased.</p>	<p>Odds of never having mmg also lower in areas 70 to 100% H</p> <p>Lower income areas</p> <p>And for younger women (ages 30 to 44 compared to ages 45 to 59)</p>
Wells BL, Horn IW. Targeting the underserved for breast and cervical cancer screening: the utility of ecological analysis using the National Health Interview Survey. Am J Public Health. 1998 Oct;88(10):1484-9.	Compare characteristics of those who have/have not had mmg, CBE, and Pap using NHIS	Retrospective from database Geographically diverse population (Connecticut, Atlanta and Seattle-Puget Sound)	<p>N=4005 Age = 67+ and on medicare for 2 years Data on race, marital status, age, SES 4% AA</p>	<p>Previous mmg use significantly contributes to black-white difference in stage at diagnosis.</p>	<p>Explained 30% of excess late-stage BC among AA. Black women were overrepresented among nonusers (35% to 22%) and underrepresented among regular users (11% to 19%) Late-stage disease diagnosed more frequently in AA women.</p>
McCarthy EP, Burns RB, Coughlin SS, Freund KM, Rice J, Marwill SL, Ash A, Shwartz M, Moskowitz MA. Mammography use helps to explain differences in breast cancer stage at diagnosis between older black and white women. Ann Intern Med. 1998 May 1;128(0):729-36.	Examine relationship between previous mmg use and BC stage at diagnosis for older AA and W women.	Randomized control trial 3 conditions (1 letter, 2 letter, 0 letter) n=1966	<p>Determine if patient reminders would significantly effect mmg use.</p>	<p>Letters had no impact</p>	<p>Those with prior mammograms and commercial health insurance were more likely to be rescreened. Age had no significant effect.</p>
Simon Ms, Gimotty PA, Moncrease A, Dews P, Burack RC. The effect of patient reminders on the use of screening mammography in an urban health department primary care setting. Breast Cancer Res Treat. 2001 Jan;65(1):63-70.				<p>Low levels of mmg use overall 3 conditions.</p>	

<p>Is race associated with timelines of follow-up care after abnormal mmg?</p> <p>Chang SW, Kerlikowske K, Napoles-Springer A, Posner SF, Sickles EA, Perez-Stable EJ. Racial differences in timeliness of follow-up after abnormal screening mammography. <i>Cancer</i>. 1996 Oct 1;78(7):1395-402.</p>	<p>N=317 Age= 33 to 85 mean=52 48% over 50 With abnormal screening mmg 64% W; 16% H; 12% Asian; 8% AA in SanFrancisco</p>	<ul style="list-style-type: none"> - Abnormal screening mmg interpretation not sign. diff by race. - Median time to final disposition differed sign. by race (12 days W and 19 days nonW) - Median time to 1st diagnostic test sign. (7 days W and 15 days nonW) - Overall difference from 1st diag to final disp. Not sign different (explained by lag to 1st diag.) - Age not found to be sign. predictor of follow-up time <p>Initial positive associations bn fatalism and: Age, race Initial negative associations bn education level and MD recommendation</p> <p>30% of the sample had not participated in mmg in previous 2 years. 13% never had mmg.</p> <p>Bivariate analyses: Sign diff in mean fatalism scores by: Age, race, education, MD recommendation, and insurance</p> <p>X2 for demographics/resource/compliance w screening</p> <ul style="list-style-type: none"> - older women less likely to be screened in previous 2 years - race and place of residence not associated w screening - Resource var. associated w noncompliance included: MD recommendation, insurance, having service paid by Best Chance Network <p>T-tests compare mean fatalism for compliance and noncompliance:</p> <ul style="list-style-type: none"> - mean fatalism for AA in compliance was sign lower than for noncompliant AA. - Same difference not found for W! <p>Fatalism did not add to the explanatory model when logistical regression included all variables for noncompliance.</p>

<p>Phillips JM. Breast cancer and African American women: moving beyond fear, fatalism, and silence. <i>Oncol Nurs Forum</i>. 1999 Jul;26(6):1001-7.</p> <p>Explore beliefs, attitudes and practices related to BC screening for low & mid income AA women.</p>	<p>3 focus groups...all AA women 90 min 8 mid income 8 service workers 10 unemployed ages 40-65 recruiting and snowballing used to get sample moderator and assistant moderator to conduct groups both AA similar settings...\$25 payment to all</p> <p>?s included “What are primary health concerns of AA women?” and “Compared to other ethnic groups, how would you rate the health status of AA women?”</p>	<p>Demographics: - 7 <HS - 19 at least HS - 13 did BSE monthly - 19 had CBE every 6 to 12 mo. - 6 had no mmg (4 service and 2 unemp.) 1 unemp. Never had CBE</p> <p>Major feelings associated w/BC: - Panic and Fear (all groups) - Death and amputation ONLY TEACHERS mentioned mmg and early detection.</p> <p>Secrecy and silence Power of prayer Screening associated with fear and this was a reason not to get screened...didn't matter if early detection best assurance of cure</p> <p>Barriers in Health Care System: - money - racial differences in treatment - only go to doctor if something is wrong - transportation - no guarantees - physician discouragement (?) surgery associated with worsening of condition HMO's</p>	<p>REALLY GOOD STATS FROM ACS ON MORTALITY AND BC! There are some quotes in here that would support the importance for early detection and would be additive to research component of lit review.</p> <p>- AA women with newly diagnosed 1st primary BC were sign. younger than W women. - AA women almost 2X as likely to be diagnosed before 50. AA women had lower SES, education, and occupation</p>

	<ul style="list-style-type: none"> - physicians refused access to White patients more often than AA patients! - 76% participation rate - Used TNM stage established by American Joint Committee on Cancer. 	<ul style="list-style-type: none"> - AA women were 3X as likely to be obese - Risk of diagnosis at TNM II or > was twice. more for AA women than W. - W women 2X as likely to ever have mmg. AA women were sign. more likely to NEVER have mmg or to NOT have mmg in 3 years prior to diagnosis. - Race-mmg association greater in younger women. - Sign. more W women reported physician recommendation for mmg. Prior to illness. Adjustment for SES, education and occupation did not alter race-mmg association. - History of screening mmg was protective against later stage of BC only in white women! 	<p>There are a few blanket statements that relate SES to BC that may be used as "filler" if needed.</p>
Baquet CR, Commisskey P. Socioeconomic factors and breast carcinoma in multicultural women. <i>Cancer</i> . 2000 Mar 1;88(5 Suppl): 1256-64. Review.	This is a review of literature on SES and ethnicity as it is associated with BC rates.	<p>Examined relationship of Age, ethnicity, income, and urbanization on BC diagnosis at early stage.</p> <p>In California based on existing data set from California Cancer Registry.</p>	<p>N=85, 808 From 1994-1997</p> <p>Larger % of non-Hispanic white women and younger women were diagnosed at early stage.</p> <p>Larger % were diagnosed in more recent years.</p> <p>12 % increase in diagnosis of in situ tumors b/n 1994 and 1997.</p> <p>Groups at high risk of later diagnosis were elderly, H, AA, and those living in nonurban areas.</p> <p>10-20% higher mortality rate for AA than W.</p>
Newman LA, Carolin D, Simon M, Kosir M, Hyrnuk W, Demers R, Schwartz AG, Visscher D, Peters W, & Bouwman D. Impact of Breast Carcinoma on African-American Women: The Detroit Experience. <i>Review. Cancer</i> . 2001 May 1;91(9):1834-43.	Review of literature on AA women with BC.		<p>One study on follow-up that we don't have was cited: McCarthy BD, Yood MU, Boohaker EA, Ward RE, Rebner M, Johnson CC. Inadequate follow-up of abnormal mammograms. <i>AM J Prev Med</i> 1996;12:282-8.</p> <p>Found: 34% W with inadequate follow-up compared to 49% AA!</p>
Lauver, DR, Dane J. A motivational message, external barriers, and mammography utilization. <i>Cancer Detect</i>	Test interaction of motivational message with external barriers on women's mmg use in SES dis	<ul style="list-style-type: none"> - N=101 51 to 80 yrs. (avg=64) - no mmg in prior 18 mos. - ID'd by chart review at urban 	<p>Increased mmg use for women without external barriers but not for those with barriers.</p>

	advantaged groups. H1: Women who rcvd message and had no barriers would be more likely to obtain mmg.	- hospital mmg clinic. - Excluded women under 50 and over 80 and women who couldn't speak English. - 55% W and 45% AA. - Random assignment done for each group separately to control race. - Control received no message and Intervention received message and brochure. - Phase II involved getting consent from control and assessing screening bx and barriers for all participants. At this time nurses discussed rationale and recommendations for screening w/control. - Measure = whether mmg was rcvd b/n message delivery and PII.	Racial differences: AA used mmg more than W. AA had less education and higher perception of BC risk but these var. unrelated to mmg use.
Barroso J, McMillan S, Casey L, Gibson W, Kaminski G, Meyer J. Comparison between African-American white women in their beliefs about breast cancer and their health locus of control. <i>Cancer Nurs.</i> 2000 Aug;23(4):268-76.	Looked at HBM and HLOC to evaluate differences in knowledge and beliefs about BC between W and AA women.	Convenience sample from health care facilities in Florida. Health Screening Questionnaire (psychometrics presented...good internal consistency, construct validity, and T/rT reliability) distributed to participants along with demo. Measure. 374 questionnaires returned (89%) 152 AA and 197 W ages 19-93 with mean=51.6 AA and 54.1 W.	More AA indicated: - Health is matter of luck - They worry about health - Could not or were unsure they could prevent BC. - Were unsure that 50% of those with cancer can be cured - Were unsure of benefits of early diagnosis Internal HLOC was equal for W and AA. BUT... - AA women were sign more likely to believe in chance and depend on powerful others for health.
Moore RJ. African American women and breast cancer: notes from a study of narrative. <i>Cancer Nurs.</i> 2001 Feb;24(1):35-42; quiz	Interviews with breast cancer survivors	Small sample of AA women's perspectives presented	Level of Education was significantly related to beliefs about seriousness of BC for white women but not for AA women. For both AA and W women, level of education was sign. related with belief in Chance and Powerful Other (i.e. better education = less belief in chance) The most mentioned idea that came out of this was the absence of AA survivors in media, absence of AA prosthetics, and the need for more culturally sensitive models of BC presentation and care.

<p>Gulitz E, Bustillo-Hernandez M, Kent EB. Missed cancer screening opportunities among older women: a review. <i>Cancer Pract.</i> 1998 Sep-Oct;6(5):289-95.</p> <p>Presents analysis of literature and findings from interview/surveys with professionals in BC field. Discusses perceived barriers to BC screening.</p>	<p>218 MD's, 54 DO's, 178NP's, 46 CNM's. n=496 respondents out of 2052 randomly sampled (see next article)</p> <p>Open ended survey's and interviews (telephone and face to face)</p> <p>Qualitative analysis</p>	<p>Patient Barriers:</p> <ul style="list-style-type: none"> - reasons women did not seek out preventive health services - this is mostly reasons that providers felt that women were not directed to have screening and perceptions of why those women wouldn't follow through - poorer, older women harder to motivate women with comorbid conditions - if provider suspects woman would not follow through - not wanting to further burden a woman <p>Provider Barriers:</p> <ul style="list-style-type: none"> - No personal commitment to prevention ...focus on treatment of acute conditions - Inexperience in patient education - Not wanting to offend patients - Unsure of clinical skills <p>Practice Barriers:</p> <ul style="list-style-type: none"> - small practices are overwhelmed with acute cases and may have little time for preventive care. - Lack of personnel - Belief that screening should only be discussed during well visits <p>Access Barriers:</p> <ul style="list-style-type: none"> - difficulty of referral and same day scheduling - cost - limited screening facilities - location of screening facilities 	<p>Older providers in small or rural practices who specialized in geriatrics or adult health were least likely to screen older asymptomatic women.</p> <p>30% of physicians and 43% of nurses concur that mng is not financially accessible to most of their women patients.</p> <p>10% of providers were uncertain and 12% agreed with a statement that annual mng in women over 50 is too frequent! That's 22% who don't</p>
	<p>Gulitz E, Bustillo-Hernandez M, Kent EB. Missed cancer screening opportunities among older women: A provider survey. <i>Cancer Pract.</i> 1998 Nov-Dec;6(6):325-32.</p>	<p>Quantitative survey component of previous</p>	<p>See previous</p>

<p>Erwin DO, Spatz TS, Stotts RC, Hollenberg JA. Increasing mammography practice by African American women. <i>Cancer Pract.</i> 1999 Mar-Apr;7(2):78-85.</p>	<p>Looks at effectiveness of Witness Project. Uses cancer survivors to promote screening in rural underserved AA women.</p> <p>Women in church and community groups in 2 counties in rural Arkansas</p> <p>There was only one potential site in this area to receive screening mmg.</p> <p>Intervention and control group</p> <p>AA role models in intervention group did presentations in local churches and community groups using a model (with appropriate skin tone) to show how to do BSE, talked about personal experience with cancer and gave out vouchers for free mmg.</p>	<p>Quasi-experimental pre/post</p> <p>Women in church and community groups in 2 counties in rural Arkansas</p> <p>There was no sign. changes in control.</p>	<p>know!!!! And these are the experts</p> <p>Women in intervention reported a significant increase in BSE (49.0 % to 65.4%) and MMG (52.4% to 64.4%) screening behaviors.</p> <p>Only b/n 9 and 46% of those tests were done.</p> <p>Younger women more likely to be screened.</p> <p>Family practice physicians and residents varied from 58 to 76% in recommending appropriate screening</p> <p>Only b/n 9 and 46% of those tests were done.</p> <p>Table of Barriers to Cancer Screening</p> <p>Equivalent baseline characteristics between intervention and control.</p> <p>Intervention:</p> <ul style="list-style-type: none"> - 31% had mmg at baseline; 56% had mmg at follow-up (sign) - physician referral effect on screening rates at baseline 38 to 28%; at follow-up 60 to 31% - proportion of women reporting fewer barriers at follow-up 40% <p>Comparison:</p> <ul style="list-style-type: none"> - 33% had mmg at baseline; 40% had mmg at follow-up (nonsign) - proportion of women reporting fewer barriers at follow-up 10% <p>Intervention:</p> <ul style="list-style-type: none"> - used baseline data - Precede/proceed, HBM and social learning theories and PENIII for cultural sensitivity
	<p>Blair KA. Cancer screening of older women. <i>Cancer Pract.</i> 1998 Jul-Aug; 6(4):217-222.</p>	<p>Are family practice physicians and residents screening older women for cancers as recommended by ACS, the Guide to Clinical Preventive Services, and Healthy People 2000?</p>	<p>Retrospective chart review</p> <p>Random sample from 660 women seen b/n July 1, 1992 and June 30, 1993 over age 60.</p> <p>N=201 charts</p> <p>Predominantly white (85%)</p> <p>Baseline:</p> <ul style="list-style-type: none"> - random samples selected for interview - knowledge attitudes, barriers, use of screening - 78% response rate overall with N=125 intervention and N=123 control <p>Follow-up:</p> <ul style="list-style-type: none"> - only women in communities during intervention period were sampled - 75% response rate N=168 intervention and N=134 Control <p>Intervention:</p> <ul style="list-style-type: none"> - used baseline data - Precede/proceed, HBM and social learning theories and PENIII for cultural sensitivity

	<ul style="list-style-type: none"> - community events, educational programs, brochures, mass media, monthly classes by lay health educator, birthday cards, targeted mailings and door knob hangers, one-on-one educational sessions. <p>Winston Salem – intervention</p> <ul style="list-style-type: none"> - 9 housing communities - 908 women; predominantly AA - majority over 65 - final N=125 <p>Greensboro – control</p> <ul style="list-style-type: none"> - 18 housing communities - 1021 women; predominantly AA - majority over 65 - final N=123 <p>Face to face interviews</p>	<p>Advocates incorporating knowledge of cultural themes, beliefs and attitudes of AA women toward screening, detection, and BC in general.</p> <p>BC=death sentence Injury of breast and blood toxins = BC Limited efficacy of mmg Spiritual and religious beliefs Belief that BC is white woman's disease</p> <p>Mmg <1 year:</p> <ul style="list-style-type: none"> - 39% age 40-44 - 47.2% age 45-49 - 62% age 50-69 <p>differences in MMG use: not completed HS = 73.7% completed HS= 79.2%</p> <p>Response categories were: never, <1 year ago; 1-2 years ago; 3-4 years ago, and 5 or more years ago.</p> <p>HS+1 = 80.1 More education = more mmg</p>	<p>Greater mmg use among women with family history and those with cystic disease</p> <p>Willingness to pay varied by ethnicity With average overall of \$130</p>
Phillips J, Smith ED. Breast cancer control and African American women: a review. <i>Cancer Invest.</i> 2001;19(3):273-80. Review.	<p>Review of literature on BC in AA women</p> <p>Same author as Fatalism articles</p>	<p>Mail survey of 64, 350 AA women ages 21 to 49</p> <p>Report based on responses of 27,632 AA women b/n ages 40-69</p> <p>Asked when last mmg was. Response categories were: never, <1 year ago; 1-2 years ago; 3-4 years ago, and 5 or more years ago.</p>	<p>W, H, AA, Filipino, And Chinese women</p> <p>Some information on demographics and screening behaviors</p>
Cozier Y, Palmer JR, Rosenberg L, Adams-Campbell LL. Recent mammography use among African American women. <i>Ethn Dis.</i> 2001 Spring-Summer;11(2):188-91.	<p>Large national study to assess mmg use in AA women in 1995</p> <p>BASIC STATS ON MMG USE</p>	<p>Survey on how much low-income women of 5 different ethnicities were willing to pay for mmg.</p>	<p>Survey on how much low-income women of 5 different ethnicities were willing to pay for mmg.</p>

Schneider TR, Salovey P, Apanovitch AM, Pizarro J, McCarthy D, Zullo J, Rothman AJ. The effects of message framing and ethnic targeting on mammography use among low-income women. Health Psychol. 2001 Jul;20(4):256-66.

Investigates impact of video messages on mmg use and attitudes. Whether differences exist in the way that video message is framed (Gain or loss and multicultural vs. targeted). Flyers invited women 40 years and over to participate

Convenience samples from 2 inner-city community health clinics and from public housing developments
- 43% AA, 27% W, 25% Latina, 2% AI, 1% Asian, 3% other
multicultural vs. targeted.

Women in clinics were invited to participate and completed questionnaire before and continued experiment after appointment

\$10 participation incentive

Random assignment to 1 of 4 conditions:
all watched videos,
- loss-framed multicultural
- gain-framed multicultural
- loss-framed targeted
- gain-framed targeted

All participants were to answer questionnaire before and after that assessed demographics and screening behavior
Measures taken at 6 month and 12 month follow-up

Bernstein J, Mutschler P, Bernstein E. Keeping mammography appointments: motivation, health beliefs, and access barriers experienced by older minority women. J Midwifery Womens Health. 2000 Jul-Aug;45(4):308-13.

Investigates willingness and ability of women over 50 to keep mmg appts.
Peer intervention to increase mmg
Differences bn English and non-English speaking women

Immediate:
- Loss framed messages elicited greater negative affect
Ethnically targeted videos had higher ratings of video model similarity and were rated as more important to participants families and backgrounds.

6 month:
- loss framed multicultural condition participants were more likely (1.8X) to report mmg than gain framed multicultural condition
framing and targeting use differed by ethnicity
- AA women's use of mmg not improved by intervention.
- W and Latina's more persuaded by loss-framed multicultural message

12 month:
effects were not significant
Suggestion for more studies using booster to prevent fading

English speaking were less likely to keep appointment – no mention if race was a factor here!!!!!!
Identified barriers:
- Fear 46%
- Transportation 38%
- Cost 22%
- Preference not to know 24%
- Pain 15%
- Family responsibilities 14%

	<p>Peer educators did intervention</p> <ul style="list-style-type: none"> - gave info on importance of mng - assisted review of pros and cos of making/keeping mng appt. - aided in development of self-defined plan for breast health maintenance - assessed mng readiness - set up mng appt if requested. <p>Follow up telephone survey at 3 months with 66% response rate</p>	<p>Data from 28237 all patients with 4 types of cancer in Florida in 1994</p> <p>Evaluated stage at diagnosis, race, SES, type of insurance (or no insurance)</p>	<p>Results for BC showed that those insured by Medicaid or uninsured were more likely to be diagnosed with late stage disease.</p> <p>AA or H more likely to be diagnosed late independent of insurance</p>
Roetzheim RG, Pal N, Tenant C, Voti L, Ayanian JZ, Schwabe A, Krisscher JP. Effects of health insurance and race on early detection of cancer. <i>J Natl Cancer Inst.</i> 1999 Aug;18:91(16):1409-15.	<p>Relationship of time at diagnosis with type of health insurance</p>	<p>Examines trends in screening use for cancers across 1987, 1992, and 1998 national surveys.</p>	<p>Evaluation of the National Health Interview Survey</p> <p>Use of MNG almost doubled b/w 1987 and 1992. - 1998 - slower rate of increase up to 1998.</p> <p>67% of women over 40 received mng within last 2 years.</p> <p>Racial/ethnic differences in mng use for AA shown in 1987 disappeared by 1998.</p> <p>H women screened at lower proportion.</p> <p>Low income and uninsured women remain underserved.</p>
Breen N, Wagener DK, Brown ML, Davis WW, Ballard-Bash R. Progress in cancer screening over a decade: results of cancer screening from the 1987, 1992, and 1998 National Health Interview Surveys. <i>J Natl Cancer Inst.</i> 2001; 93: 1704-1713.			
Phillips JM, Cohen MZ, Tarzian AJ. African American women's experiences with breast cancer screening. <i>J Nurs Scholarsh.</i> 2001;33(2):135-40.	<p>Describe meaning and breast cancer screening experiences of AA women</p> <p>SAME AUTHOR AS FATALISM</p>	<p>Very qualitative with small sample 8 low-income and 15 mid-income AA women</p> <p>unstructured open-ended interview</p> <p>describe experiences with BC screening (including self and physician exam and mng)</p> <p>60-90 minute interviews included demographics</p> <p>identified universal themes</p>	<p>More low income women expressed problems with lack of access to health care</p> <p>Less than optimal screening rates in both groups</p> <p>Themes</p> <p>Lack of health insurance</p> <p>Relationships</p> <p>Religion</p> <p>Caring and respectful physicians were more important than racial and ethnic attributes in determining trust.</p> <p>Women who were confident in their skills, comfortable with their bodies, and had sense of self-</p>

<p>Coleman EA, O'Sullivan P. Racial differences in breast cancer screening among women from 65 to 74 years of age: trends from 1987-1993 and barriers to screening. <i>J Women Aging.</i> 2001;13(3):23-39.</p>	<p>Compare BC screening rates and barriers for AA and W women and identify trends between 1987 and 1983 Reports on 3rd survey wave</p>	<p>N=6061; 16.8% AA and 83.2% W Computer assisted telephone interviews, mailed questionnaires, and field interviews</p>	<p>Physicians recommendation, level of education, and health status were sign associated with mmg use.</p>	<p>esteeem were more likely to engage in BCs. Medicare funding for MMG resulted in more use of MMG but trends differed for w and AA. W showed more substantial increase 32.6% in 1988 and 59% in 1993. Increase from 1991 to 1993 = 5.4%. AA showed less increase 26.2% in 1988 and 47.9% in 1993. Increase from 1991 to 1993 <1%.</p> <p>Physicians recommendation, level of education, and health status were sign associated with mmg use.</p> <p>Physicians were more likely to recommend mmg for W married women with education beyond HS and >\$20,000. income.</p> <p>No sign. difference found for frequency of mmg use and CBE</p> <p>THERE WERE NO SIGN. DIFFERENCES IN INCOME OR FAMILY HISTORY OF BC</p> <p>More AA women practiced monthly BSE</p> <p>W women had sign. higher mean score for perceived barriers to mmg and CBE</p> <p>Entire study questionnaire evaluated by experts.</p> <p>117 AA and 157 W avg. age for AA=47.62 and for W=44.71 this is statistically sign. but authors purport it is not clinically sign.</p> <p>All women were currently employed by school system and over 35!!!!!!</p> <p>Cross-sx! Telephone interviews; structured likert scale questions 8 item mood adjective checklist (POMS) with established psychometrics Attitudes Towards MMG Scale to measure beliefs about mmg. Time of last mmg use=1 nonuse=0 in last 13 months</p> <p>Women of Color were put into one category and compared with Caucasian women. Women of low SES were over represented Single women were more likely to perform monthly BSE and seek yearly MMG.</p> <p>Most women reported few barriers Women who had low negative moods, no barriers, no history of asymptomatic breast problem, had</p>
<p>Douglass M, Bartolucci A, Waterbor J, Sirles A. Breast cancer early detection: differences between African American and white women's health beliefs and detection practices. <i>Oncol Nurs Forum.</i> 1995 Jun;22(5):835-7.</p>	<p>To determine if differences exist between W and AA women with respect to frequency of use, health beliefs about mmg, CBE and BSE. What differences, if any, exist?</p>	<p>3 part descriptive survey - investigator developed Questionnaire consisting of items on frequency of use of mmg, CBE, and BSE according to ACS recommendations. - modified version of Champion's HBM scales (CHBMS). 25 additional items on benefits, barriers, and control to address use of mmg and CBE. - items used to calculate SES using Green's 2 factor formula.</p>	<p>Entire study questionnaire evaluated by experts.</p>	<p>117 AA and 157 W avg. age for AA=47.62 and for W=44.71 this is statistically sign. but authors purport it is not clinically sign.</p>
<p>Lauver DR, Kane J, Bodden J, McNeel J, Smith L. Engagement in breast cancer screening behaviors. <i>Oncol Nurs Forum.</i> 1999 Apr;26(#):545-54.</p>	<p>What variable distinguish women who engage in recommended breast screening from those who do not?</p>	<p>What variable distinguish women who engage in recommended breast screening from those who do not?</p>	<p>What variable distinguish women who engage in recommended breast screening from those who do not?</p>	<p>What variable distinguish women who engage in recommended breast screening from those who do not?</p>

	<p>Belief in likelihood of developing BC 37's on BC knowledge Facilitators / Barriers measured with Melnik's Barrier Scale (1990)</p> <p>Age range=51-80 Sample from records at mng clinic or urban hospital Ability to speak English N=119</p> <p>Protocol not specific</p>	<p>private insurance and were single women of color were more likely to have had a mng in the past . year.</p> <p>PAHS scores increased significantly for women who had more than a HS education vs. those who did not. 24% of the variance in the PAHS was attributed to family annual income level. - higher income = higher PAHS score</p> <p>51% of the sample perceived some degree of prejudicial treatment in healthcare services with 22% reporting personal experience</p> <p>Prejudicial treatment : small sign. difference between AA and W with AA experiencing more Small sign difference for poor women Sign. difference for lesbian vs. hetero and bi women.</p> <p>25% reported little or no healthcare use. Significantly lower HHSU scores for women reporting experiencing prejudicial treatment</p> <p>57% of the variance in perceived access was attributed to health care habits, Spanish as the spoken language, 3 measures of financial capability Family annual income was only factor to explain unique variance</p> <p>This sample had unusually high rate of mng adherence.</p> <p>Sign. differences found for perceived access to health services, personal experience of prejudice, annual income.</p>
	<p>Facione NC. Breast cancer screening in relation to access to health services. Oncol Nurs Forum. 1999 May;26(4):689-96.</p>	<p>Examines perceptions of access to health care and the relationship between perceptions of access and BC screening bx.</p> <p>\$10 reimbursement all materials in English and Spanish</p> <p>multiple measures: - Perceived Access to Health Services (PAHS); psm given - Habits of Health Services Utilization (HHSU); psm - Perceptions of Prejudice; newly developed - Social desirability response bias accounted for by Peynold's short form of the Marlowe-Crowne; psm given also measured mng screening history; SES; and availability of health care coverage/money for healthcare</p>

<p>Champion VL, Skinner CS, Foster JL. The effects of standard care counseling or telephone/in-person counseling on beliefs, knowledge, and behavior related to mammography screening. <i>Oncol Nurs Forum</i>. 2000 Nov-Dec;27(10):1565-71.</p>	<p>Improving MMG screening Beliefs and Knowledge, decreasing perceived barriers using telephone, or in-person counseling.</p> <p>Used time post intx of 4 weeks to measure compliance with mmg screening.</p> <p>women >50 / no mmg past 15mo. From large HMO and general medicine clinic in Indianapolis</p> <p>Only 39% (1098 of 2815) contacted agreed to participate.</p> <p>Only 696 remained at follow-up.</p> <p>Calculations based on original N. 30% AA</p> <p>3 groups: no counseling, telephone, in-person</p> <p>measures included perceived susceptibility, benefits, and barriers (5 pt. likert)</p> <p>knowledge scale had 18 MC questions related to screening and BC treatment</p> <p>Stage of mmg adoption was assessed</p>	<p>No sign. differences in stage of mmg adoption pre. Post: 17% of control became compliant 30% of telephone; 33% of in-person post perceived susceptibility scores sign. higher in both intx groups.</p> <p>Perceived benefits for control sign. lower than both intx.</p> <p>Sign difference across all groups for perceived barrier scores but those in the control group were sign. higher than in both intx. Groups</p> <p>Controlling for knowledge pre, post knowledge for both intx. Sign. higher</p>	<p>Test-retest with control and random assignment to condition</p> <p>Cross sectional correlational Using Theory of Reasoned Action as basis</p> <p>Investigator created questionnaire with 237 items: 30 min interview by trained RA</p>	<p>Mean age =51 90%AA 6% H 60% unemployed mean income \$7933.</p> <p>All variables accounted for between 11-36% of variance</p> <p>Intention to have mmg positively related to influence of sign. other</p> <p>Intention to have mmg was negatively related to uncaring healthcare professional, taking too much time.</p> <p>Positive patient-provider relationships were highly associated with intention to have screening. (no direction stated)</p> <p>Subjects 339 uninsured English-speaking > 40 years old.</p> <p>*recruited from 6 cancer screening sites</p>
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		<p>participating in free BC and cervical screening *site coordinators identified potential study subjects (no details)</p> <p>Because the actual results were only in text (except for demographics), it was difficult to determine direction of some of the “associations”</p>
Frazier EL, Jiles RB, Mayberry R. Use of screening mammography and clinical breast examinations among black, Hispanic, and white women. <i>Prev Med</i> . 1996 Mar-Apr;25(2):118-25.	<p>Examines relationship of race/ethnicity and screening bx's. Age, education, region, marital status, family income are also evaluated.</p> <p>N=22,657 (9.1%AA, 3.1%H, 87.8%W)</p>	<p>Based on data analysis from a large state-based telephone survey. Includes data from 44 states.</p> <p>47% AA and H reported having recent mmg 50% W reported recent mmg 68% AA, 59% H, and 66% W reported recent CBE.</p> <p>Lowest screening rates for mmg and CBE were reported by >50 y/o, <HS education, and having routine exam >1 year ago.</p> <p>35% of all women said they had never had a mmg (8016) no demographics presented</p> <p>of those never having mmg, reasons included:</p> <ul style="list-style-type: none"> - 33% said they did not need it (33% AA and W, 43% H) - 30% said no physician recommendation (36% AA, 26% H, 30% W) - 8% said it was too expensive or lack of insurance - less than 1% had never heard of mmg. <p>AA women ages 50-64 were less likely to report having screening mmg than AA women 65+!!!</p> <p>Considering that research reports earlier incidence of BC for AA and higher stage at diagnosis.....*****</p>
Husaini BA, Sherkat DE, Bragg R, Levine R, Emerson JS, Mentes CM, Cain VA. Predictors of breast cancer screening in a panel study of African American women. <i>Women Health</i> . 2001;34(3):35-51.	<p>Examines predictors of breast cancer screening and examines the impact of a church/community based BC education program on AA women.</p>	<p>No random assignment Pre and post with control Control was not equivalent</p> <p>All intervention groups were shown 2 videos and some of the intervention groups received reinforcement from a clinical instructor. Intervention lasted b/n 1 and 1 ½ hours.</p> <p>Measures were questions on mmg status, cancer related beliefs, social support. These appear to be created by experimenters (though this was never directly stated).</p> <p>A 20 item measure of depression scale was used to assess the impact of</p>

Miller AM, Champion BL. Attitudes about breast cancer and mammography: racial, income, and educational differences. <i>Women Health</i> . 1997;26(1):41-63.	<p>Examines differences between AA and W attitudes toward, and knowledge of BC and mng.</p> <p>N=1083 (78% W and 22% AA)</p> <p>Church women</p> <p>Mean age =65.7</p> <p>Mailed survey (researcher developed)</p> <p>Measures of susceptibility, benefits and control derived from HBM.</p> <p>Initial contact by phone with followup letter.</p> <p>Advertisement in churches to increase participation.</p>	<p>Depression on mng participation.</p> <p>Cross sectional correlational</p> <p>85% from both races had ever had mng</p> <p>22.1% of W and 17.4 % of AA followed mng guidelines for 3 years .</p> <p>AA women had higher perceived susceptibility than W women</p> <p>Intx bn race and income for perceived benefits:</p> <ul style="list-style-type: none"> - AA low income women had highest level of perceived benefits - W women perceived more benefits as income increased. 	<p>Return rate of surveys = 45% usable.</p> <p>W women were 65% less likely to regard radiation as a barrier and 50% less likely to worry about finding BC.</p> <p>Higher barrier scores and greater perceived control for both races were less likely to have mng.</p>
			<p>LA, Kaplan CP, Bastani R, Scrimshaw SC. Determinants of adherence among health department patients referred for a mammogram. <i>Women Health</i>. 1996;24(2):43-64.</p>

APPENDIX B

REVISED-2 Research Protocol

Submitted to Department of Defense for Breast Cancer Concept Award (BC995929)

NOTE: Only attachments with required or requested changes are included with this package (Revision-2). Other materials were provided in previous packages. The following is a list of applicable attachments with this revised submission:

Attachment A:	Revised CV of Dr. Debra J. Holden
Attachment B:	Revised Consent Form
Attachment C:	Revised Interview Protocol
Attachment D:	Letters of Collaboration from Participating Local Health Agencies

1. Protocol Title:

Increasing Follow-up Rates among Minority Women with Abnormal Mammography Results or Delays in Re-Screening

2. Phase: N/A

3. Principal Investigator: Debra J. Holden, Ph.D.
North Carolina State University
Psychology Department
Box 7801
Raleigh, NC 27695-7801
(919) 662-3896 (office phone)
debra_holden@ncsu.edu

Dr. Holden's current curriculum vita is Attachment A to this revised package.

Significant Contributor: Rebecca D. Martin, Ph.D.
Independent Consultant
Cancer Epidemiologist and Researcher

4. Location of Study:

North Carolina Breast and Cervical Cancer Control Program
Dianah Bradshaw, RN, MSHA
Director, Quality Assurance and Patient Services
Breast and Cervical Cancer Control Program
1915 Mail Service Center
Raleigh, NC 27699-1915
Dianah.Bradshaw@ncmail.net

RESEARCH PROTOCOL

BC 995929

Submitted March 2002

Revised May 2002

Revised-2 July 2002

5. Time Required to Complete: May 1, 2002- December 31, 2002

6. Objectives:

To better understand why minority women are less likely to follow-thru with recommendations to obtain mammography re-screening in a timely manner or to receive diagnostic care for an abnormal mammography result and use the findings from this target group to design an initiative to address this disparity.

Study Objectives:

Immediate—To be completed as part of this study

- To interview 30 minority women, age 50 years or older, in 3-4 North Carolina counties who have received mammography re-screening as recommended for each of the past three years; and,
- To interview 30 minority women, age 50 years or older, in 3-4 North Carolina counties, who have not received the recommended mammography re-screening or follow-up care during any of the past 3 years.

Intermediate—To be completed as part of this study

- To develop, in conjunction with North Carolina Breast and Cervical Cancer Program (NCBCCCP), an innovative, community-based intervention based on findings from this study that will help to overcome identified problems and barriers to breast cancer re-screening and follow-up.

Ultimate—as a long-term outcome for the NCBCCCP

- To improve the rates of re-screening and follow-up for breast cancer among minority women by better understanding the variables that predict these behaviors.

7. Study Population:

- a. **Describe the target population:** Minority women (primarily African or Native American women, all English speaking), ages 50 years or older, receiving at least one mammogram during the past 3 calendar years (1999-2001) through any of 3-4 local agencies contracting with the NCBCCCP will be possible study participants. These local agencies will be selected by NCBCCCP based on state-based epidemiological data from the reports generated by the state program from data supplied from local agencies on the women they screen. This data set will be used to identify 3-4 counties within North Carolina that have had a high rate of late-stage diagnosis of breast cancer among minority women. Women who have obtained either screening or follow-up later on in their disease progression are more likely to have their cancer identified at a late stage. Studies have shown that a disproportionate number of these women are African American or from other minority groups. Through collaboration with the NCBCCCP, the local public health agencies in these

selected areas of high need will be contacted. The focus of the study will be on two groups of women: those who have obtained a mammogram at least 2 of the past 3 years, as recommended for their age group, and those who have not obtained a mammogram all 3 years, or have not returned to receive diagnostic care after receiving an abnormal mammogram result.

- b. Describe the methods for obtaining sample: Based on state epidemiologic data, local agencies will be recruited for participation in this study. Sampling of the women to recruit is not random but is stratified by age, race, and mammography utilization over the past 3 years (1999-2001 calendar years). Only women who are 50 years or older and non-white will be selected for study participation. As mentioned above, their mammogram utilization either has to be high (having had a mammogram for at least 2 of the past 3 years) or low (having had a mammogram for only 1 of past 3 years), or failing to return for follow-up after receiving an abnormal mammogram result. The most accurate description of the sampling strategy is convenience. Using a list of participant identifiers (coded as numbers, not names) supplied directly from the NCBCCCP to the local clinic staff, participating local agency staff will verify that women meet one of these two criteria and mail the study's consent form to the woman, with the lead letter on agency letterhead, requesting she return it to the researchers. Women who are not representatives of a minority population will not be included since they are more likely to obtain re-screening or diagnostic care as recommended.
- c. Inclusion of pregnant subjects: Study participants will all be 50 years or older, past child-bearing years so determining pregnancy status is not relevant to this study.
- d. Sample size for study: Study includes a total of 60 completed interviews. The target for the study is to complete 30 interviews with women who have received screening as recommended and with 30 women who have not. However, since the health agencies are not able to provide the researchers with the results of each woman's test, we will not know how many women in each group we have obtained until completing each interview (we ask questions related to this in the interview). Therefore, we plan to recruit up to 75 total women in order to complete 60 interviews that meet the criteria of half the women receiving screening regularly, and half who have not. This sample size was not calculated statistically since this is a pilot project to determine the issues that should be addressed in developing a local intervention. This sample size was also negotiated with NCBCCCP as what seemed feasible to them in terms of the women who would meet the criteria for this study AND agree to participate, given the time frame for conducting this study.

- e. **Survey instrument:** The interview items were developed for this study (Attachment C) through a thorough and systematic review of the literature on relevant topics. Using peer-reviewed data as a guide, the PI then utilized items created on previous studies she has led that have been tested and validated. For many items however, the information has to be obtained through open-ended questions that are rarely standardized and certainly not psychometrically tested. Drafts of the instrument were then reviewed by the researchers for this project and the NCBCCCP staff. The finalized instrument will be used for conducting interviews for this study.
- f. **Data Analysis Plans** include preparing a thorough set of written notes, enhanced by the transcription of audio tapes, from each of the interviews completed. Once these notes have been prepared, current and rigorous methods for analyzing qualitative data will be utilized to identify themes across the respondents and prepare findings for the study (Miles & Huberman, 1987). Some of the findings will be summarized quantitatively, such as the questions in Sections I, II, and V. In these sections, an interviewee is asked to provide answers to mostly close-ended questions. The following provides a sample table of how these findings may be presented:

Sample Table _____. When did you last see a doctor or nurse for your breast health?

Responses	#	%
Within the past year		
1-2 years ago		
More than 2 years ago		

Other findings will need to be analyzed qualitatively, such as the majority of questions in Sections III-IV. For these, all interview data will be coded for themes, based on the domains of questions asked in the interview setting. For example, one area of questioning includes an understanding of their experiences in getting mammograms (Section IV, Questions 1-2). Codes will be developed to capture all types of responses. Two people will review each set of interview responses. One person will be responsible for coding the responses and the other will be responsible for checking the codes against their own results in order to determine reliability of findings. Where possible, quantitative findings of the data will be provided. For example, the questions noted may appear in a summary table such as the following:

Sample Table _____. Positive aspects or reasons for obtaining mammograms

Response Provided	Number of Interviewees providing response
It helps me take care of myself	
My family thinks it's important	
It helps me not worry about my health	

8. Protocol Design: The following outlines the proposed methodology in sufficient detail to show a clear course of action, followed by an explanation of each item specified in the protocol guidelines.

Local public health agencies contracting with the NCBCCCP will be eligible for participation in the study. They are required by NCBCCCP to provide monthly data on the women they provide mammograms to and various characteristics of her screening experience (such as test results, demographics, etc.). The researchers for this study do not have access to this data set. However, NCBCCCP has agreed to analyze their mammogram screening data for minority women 50 years of age or older to identify areas of the state that seem to be the most prone to have women who do not return for screenings as recommended. Based on this analysis, NCBCCCP will notify us of which 3-4 local agencies they suggest we work with in recruiting women. The researchers will then meet individually with the staff at the local agency (i.e., the clinic nurse and possibly the local health department director) to explain the study and procedures for recruiting women. NCBCCCP will provide a list directly to the local clinic nurse of the patient identifiers (data are coded by identifiers, not names) for women qualifying for this study. The researchers will not be permitted to see this list or know the results of the women since the agencies do not have the consent of the women to provide this information. The nurse will then access each patient's medical record to ensure that the data recorded matches her chart and verify that she hasn't left the area.

Once the nurse verifies the women who are eligible for in the study, they will mail consent forms provided by the researchers (Attachment B) to women who qualify for inclusion in the study. Study selection criteria will be explained to the agency staff, including: 1) women representing a minority population; AND 2) women who have obtained re-screening mammograms as recommended for at least 2 of the past 3 years OR have NOT obtained regular re-screening and/or diagnostic care as recommended within the past 3 years. Once these women are identified

by the local agency, their staff will mail the consent form to each woman to be returned directly to the PI (Attachment B). Two copies of the consent form will be mailed by the local agency to the woman and accompanied by a lead letter on agency letterhead and a stamped, self-addressed envelope for returning a signed consent directly to the researcher. The women will be directed to keep a copy of the consent form for herself. A witness form will also be enclosed in each envelope so that the woman can consent to participate in the study even if she isn't able to read the consent form. Each consenting woman will then be contacted by phone to schedule a face-to-face interview at her convenience.

Participation will be completely voluntary and confidential and it will be explained to her that her involvement (or not) will not impact any future care provided by the local agency. Once they agree to be interviewed, the researcher will arrange for a 1-hour face-to-face interview to be conducted at a conveniently located public building in her area, such as a library, the health department, or a senior health center. Efforts will be made to provide a location that respects her privacy in providing responses (such as a private room in the local library). Each of the women completing at least half of the interview will receive a \$50 compensation. Part of the \$50 compensation can be used by the woman to cover her transportation costs to the interview site. For women who are not able to travel to a convenient location (such as she is disabled or has limited access to transportation), but she consents to participate in the study, she will be provided the option of completing the interview over the phone. This option will be provided only as a last resort to obtaining information from women who might otherwise drop out of the study.

Face-to-face interviews for this study are considered to be the best methodology, but telephone interviews could be substituted if necessary. The purpose of the interview will be to talk to the women about their understanding of the results they received, what they have done to obtain care since receiving their abnormal results, barriers they had to overcome to obtain any care that they have, or reasons she has or has not obtained care (Attachment C). The notes from this interview will be written by the interviewer and audio recorded. After the interview, the interviewer will use the audio recorded tapes to complete the written notes so that the data collected from each individual woman will be thorough. Once the tapes have been used to provide more details to the written notes, they will be labelled according to the date the interview was conducted and the number of respondents for that date (i.e., the woman interviewed on June 15, who was the 3rd person interviewed that day, would be coded as 3-6.15, etc.). The written notes and tapes will be coded so that they are linked to each other but not to the individual woman who is interviewed. Once the tapes have been used to enhance the written notes, they will be maintained in a locked file that the PI only has access to until the conclusion of this study. At that point, their contents will be erased or the tapes otherwise destroyed. The contact information is used strictly to locate the women and invite their participation and maintained in a log to determine if she has been

reached for scheduling an interview. This log will be maintained in a locked secure file cabinet with access only by the research team. Upon completion of the interviews, the log will be destroyed.

- a. **Subject Identification:** Once a woman consents to the study by returning a signed form, her contact information will be entered into a log that helps the researchers keep track of where she is in the process of data collection. The log will track information on how to reach her, attempts that have been made to reach her, and dates of when the interview is scheduled. This log will be kept in a locked, secured file that is only accessible to the research staff. Once all of the interviews have been completed, this log will be maintained in a locked file for a minimum of two years after the completion of the study. All data collected and entered for analysis from the interviews will be coded using unique identification codes in order to protect confidentiality and will contain only the woman's age and race, and other demographic information collected at the end of the interview. Identifier codes will be used to link the audio tapes to the written notes but individual responses cannot be linked back to respondents.
- b. **Description of recruitment process:** Explained above. There will be no advertising or recruitment materials used other than a mailing to each qualifying woman that includes the lead letter , two copies of the consent form that includes a 'short form' for women who are illiterate (Attachment B), and a stamped, self-addressed envelope to the PI, Dr. Holden.
- c. **Description of the Informed Consent process:** This process is described above in detail and supporting documents are included as attachments.
- d. **Subject assignment:** Randomization is not possible and will not be utilized for this study.
- e. **Evaluations prior to entry:** Selection for participation will be based on results of former mammograms received through the NCBCCCP. However, these mammograms are not provided as part of this study and are only a mechanism for identifying women who meet the study criteria.
- f. **Evaluations to be made during the conduct of the study:** N/A.
- g. **Clinical assessments:** N/A.
- h. **Describe the research intervention or activity that the subject will experience:** Women are consenting to participate in a face-to-face interview to discuss her understanding of the abnormal results or the need for re-screening and her rationale for the health practices she has followed. The interviews will require approximately one hour of her time. For their time and input, the women will

be provided a \$50 reimbursement for participating in the interviews. Women who complete at least 1/2 of the interview but refuse to answer some of the questions will be provided the \$50 compensation.

9. Risks/Benefits Assessment:

- a. Risk from participation in this study is minimal and is no risk for the majority of women involved. The only risk is that a few of the women will be contacted because they have received abnormal mammography results. The interviewers are highly trained on this issue and the woman will be allowed to skip or refuse to answer questions that make her feel uncomfortable.
- b. As specified in the informed consent (Attachment B), the participating women will not benefit directly from participation in this study.
- c. Compensation provided is described in the protocol design section of this document.

10. Reporting of serious or unexpected adverse events.

It is possible that by participating in the face-to-face interview a woman will be more willing to face the consequences of an abnormal result (for women that this is applicable, which will only be approximately 5-10 women). It is possible that some of the women will have been in denial about the need for follow-up and that, just by talking about this issue, will be more likely to face it and realize the potential risk to their health from these results. Both lead interviewers have extensive psychological or social work counseling experience and will conclude each interview with questions about how the women feel about their interview. The researchers will inform the women that they can return to the local health department for more specific information on next steps to take and will be provided with a sheet listing resources in their area for discussing this issue.

Adverse experiences that are both serious and unexpected will be immediately reported by telephone to the USAMRMC Deputy Chief of Staff for Regulatory Compliance and Quality (301-619-2165) (non-duty hours call 301-619-2165 and send information by facsimile to 301-619-7803). A written report will follow the initial telephone call within 3 working days. Address the written report to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

11. Description of Protocol Drugs or Devices: N/A

12. Disposition of Data:

As previously described, a log will be maintained of contact information for each woman. Throughout the study, this log will be maintained in a locked, secured file that the research staff only have access to. At the conclusion of the study, this

information will be destroyed. The interview data will not be linked to the personal contact information of each women. During the interview, the responses will be audio recorded and notes taken for use in analysis. The written notes from each interview will be linked to the audio recording through a coding system indicating the date of the interview and the number of the person responding (for example, the 3rd person on June 15 will be coded as 3-6.15 on both the written notes and audio tapes). The tapes will be used to enhance the written notes and ensure that the information each woman provided is complete and thorough. The tapes will then be stored in a locked file that only the research staff has access to. The data used in the analysis (i.e., the complete interview notes) will not be linked to the women themselves.

13. Modification of the Protocol:

Should any study procedures need to be changed, both the local IRB and all relevant contacts at HSRRB will be contacted and guidance requested on procedures to follow.

14. Departure from the Protocol:

Local IRB and HSRRB will be notified if protocol is to be changed. No departure from the protocol will be permitted for conducting interviews with individual subjects that has not already been addressed elsewhere.

15. Roles and Responsibilities of Study Personnel

Principal Investigator: (15%) Obtain cooperation with all study partners, including the North Carolina Breast and Cervical Cancer Control Program and the local agencies selected to participate. Create research protocol and study questions. Train study staff on their roles and responsibilities and supervise all activities. Conduct ½ of study interviews and oversee data analysis and reporting. Oversee budget monitoring and overall conduct of study.

Consultant (Dr. Martin, 200-240 hours total). Assist in establishing collaborative relationship with all study partners, attend meetings to negotiate study protocol, and provide input into accomplishing study goals within the study's context. Provide guidance and input into IRB package, study protocols, consent forms, etc. Conduct ½ of the face-to-face interviews. Assist in data analysis and report writing.

Graduate Student Research Assistant (25%). Conduct literature review to inform protocol development. Coordinate study activities including contacting consenting women to participate in the study (once consent is received via mail). Schedule interviews and coordinate sessions. Assist Dr. Holden in interview

sessions by being present for note-taking and audio-taping interview. Lead data entry and assist in data analysis and report writing.

Consultant (Ms. Ladner, MPH—75-80 hours). Assist Dr. Martin in conducting interviews by being note-taker and audio-taping interviews. Assist RA with data entry and provide input into review of final report of results.

Study Partner (Ms. Bradshaw, RN, MSHA, at NCBCCCP). Obtain listing of women meeting study criteria and work with local agencies to identify women and direct mailing of consents to qualifying women. Provide input into study design, interview questions, and interpretation of results.

Study Recruiters (Clinical staff from 3-4 local agencies contracting with NCBCCCP, all staff will be at least at the registered nurse (RN) level and are responsible for the operation of the local public health adult clinic that administers NCBCCCP). Meet with PI to discuss study and agree to work to mail consent forms to qualifying women. Obtain list of cases with patient identifiers (coded in numbers, not names and provided directly from the state health department to this agency for the women screened in their clinic) and review charts to ensure information is accurate and women are eligible for participation. Mail consent forms with lead letters to each woman. Answer questions from women who call about the study as possible, or refer questions to PI if needed.

16. This study is not greater than minimal risk to the participants.

RESEARCH PROTOCOL

10

BC 995929

Submitted March 2002

Revised May 2002

Revised-2 July 2002

APPENDIX C

**A-11035
HOLDEN**

MCMR-RCQ-HR (70-1n)

22 July 2002

MEMORANDUM FOR RECORD

SUBJECT: Protocol Entitled, "Increasing Follow-up Rates Among African American Women With Abnormal Mammography Results", by Debra J. Holden, Ph.D., North Carolina State University, Raleigh NC, Award No. Proposal No. BC995925, DAMD17-01-1-0580, HSRRB No. A-11035

1. **Background.** This project is part of the Congressionally Directed Research Medical Program Award. The purpose of this study is to investigate the reasons why minority women fail to return for follow-up after receiving abnormal mammography test result. The investigator will interview a total of 60 minority women, 30 of which have received screening as recommended, and 30 who have not. The study is being done in collaboration with the North Carolina Breast and Cervical Cancer Control Program (NCBCCCP), an innovative community-based intervention group, which will identify eligible subjects for the investigator. The NCBCCCP will work through 3 to 4 local Health Agencies in support of identifying the eligible subjects for this study. Initial Memorandum For Record (MFR) with recommendations was sent to the PI on 30 April 2002. The PI provided point-by-point responses to the recommendations and a revised protocol, consent form and the requested documents that were received on 28 May 2002. (See attachment 1 item 15 for point-by-point responses). A second MFR was sent to the PI on 19 July 2002 with additional recommendations. The PI submitted a revised protocol consent form and a revised interview questionnaire that were received on 12 July 2002. This MFR is the focus on the review of the revised documents. The PI responses have been incorporated into this MFR.
2. **Scientific Review.** The protocol received a scientific review by a Breast Cancer Research Program reviewer in June 2002. The reviewer made two observations about the current protocol, which the investigator has addressed, in her point-by-point responses. One observation was that the intermediate aim of the protocol is to develop an innovative community-based intervention to overcome identified problems and barriers to breast cancer rescreening and follow-up. However, the proposed strategy for this was not delineated in the protocol. Another observation made by the reviewer was that the investigator has departed from the original focus on African American women, and is now focusing on "minority women." The investigator has addressed both issues in her point-by-point responses.

3. Review by IRB of Record. The protocol received expedited review by the North Carolina State University Institutional Review Board (IRB) and was approved on 14 March 2002 under Title 45 part 46 of the Code of Federal Regulations (CFR). The continuing review date is due prior to 7 March 2003.
4. Level of Risk Assessment. The local IRB did not assign level of risk to this protocol. The investigator noted in the local IRB submission packet and the protocol that the study is no more than minimal risk. This protocol involves interviewing economically, educationally disadvantaged subjects who will be audio taped while the investigator goes through a questionnaire with the subject. The interview process does not appear to manipulate or cause harm to the subjects, and the questions are not sensitive or self-incriminating or threatening to the subjects. The payment of \$50.00 appear adequate and not coercive to this population. Although the study population is socio-economically disadvantaged, the risks to the subjects are minimal and the study could qualify for expedited review.
5. Research Design. This is a pilot qualitative study that will focus on two groups of women; those who have obtained a mammogram at least 2 of the past 3 years as recommended for their age group, and those who have not obtained a mammogram all 3 years or have not returned to receive diagnostic care after receiving an abnormal mammogram results. Selection of the women will be based on stratification by age, race, and mammography utilization over the past 3 years (1999-2001).
6. Research Objectives. The investigator has stated immediate, intermediate and ultimate objectives.

 - a. Immediate Objective.

 - (1) To interview minority women, age 50 or older, in 3 to 4 North Carolina counties who have received mammography re-screening as recommended for each of the past three years.
 - (2) To interview 30 minority women age 50 and older in 3 to 4 North Carolina counties who have not received the recommended mammography re-screening or follow-up care during any of the 3 past years.
 - b. Intermediate. To develop in conjunction with North Carolina Breast and Cervical Cancer Program (NCBCCCP), an innovative community-based intervention to overcome identified problems and barriers to breast cancer re-screening and follow-up.
 - c. Ultimate. To improve the rates of re-screening and follow-up for breast cancer among minority women by better understanding the variables that predict these behaviors. This is a long-term outcome for the NCBCCCP.
7. Study Population. Minority women primarily African or Native American women, all English speaking ages 50 years and older who received at least one mammogram during the past three calendar years from 1999 to 2001, through any of the 3 to 4 local agencies contracting with the NCBCCCP will be eligible.

8. Inclusion/Exclusion Criteria.

a. **Inclusion Criteria.** Minority women ages 50 years and older who received at least one mammogram during the past three calendar years from 1999 to 2001, through any of the 3 to 4 local agencies contracting with the NCBCCCP will be eligible.

b. **Exclusion Criteria.** There are no exclusion criteria within the stated study population.

9. Informed Consent Process. NCBCCCP will provide a list of eligible subjects directly to the clinic nurse and the Director of the selected local Public Health Agency. The investigators will meet individually with the staff at the local agency to explain the study and procedures for selecting eligible women. Patient identifiers will be coded and subjects' names will not be used. The nurse at the local agency will access each subject's medical record to verify that the subject is eligible. The nurse will then mail a Lead letter on Agency letterhead that explains the study, along with two consent forms and a stamped self -addressed envelop addressed to the investigator. The subject will then sign one consent form and mail it directly to the investigator. For those subjects who may not be able to read, a family member will read the information in the consent form to her. Another person would witness the process. All 3 persons will sign a short form provided. A contact number is provided in the consent form to contact the investigator if the subject has any questions. The subject will then be contacted by phone to schedule a face-to-face interview with the investigator or the consultant (Rebecca Martin, Ph.D.). For women who cannot travel to a convenient location, they will be provided with the option of a telephone interview. A contact information log will be maintained on each subject to track where she is in the data collection process. This log will be kept in a locked secure file cabinet. All data collected from the interviews will be coded with subject identification codes.

10. Sample Size. The target number of subjects to be interviewed is 60, 30 subjects in each group. However, the researchers plan to recruit 75 subjects because, the health agencies will not be providing them with the results of each woman's test, so they will not know how many women in each group they have obtained until they have completed each interview. The PI clarified that there was no statistical calculation of the sample size and power analysis provided by the investigator because this is a feasibility study and the sample size was negotiated with the NCBCCCP as what seemed feasible in terms of the inclusion criteria.

11. Data Collection Plan.

a. **Survey Instrument.** Questionnaire that will be used for the interview were developed through literature search on relevant topics and items created on previous studies that has been tested and validated. Some items are open-ended questions that have not been tested or standardized.

b. **Audio taped interviews.** The principal investigator and the consultant will conduct the interview in a convenient place chosen by the subject. If transportation is a problem

the subject may choose to be interviewed at home or have a telephone interview as an option. The interview will be audio taped.

12. Data Analysis Plan. Data analysis plan will include transcription of the audio tapes to enhance the written notes from the interviews. Once the notes have been prepared, the investigator will use current methods for analyzing qualitative data to identify the themes across the respondents and prepare findings for the study. Descriptive statistics on the women interviewed, including frequencies of the ages of the women interviewed, race/ethnicity, results of previous mammogram screening will be provided.

13. Risks to Subjects. The only risk that was identified by the investigator was that some subjects would be contacted because they have abnormal mammography results. Although the investigator did not recognize the audio taping of the interview as a risk, she did indicate that the audiotapes would be identified by a unique identification code.

Procedures	Risks	Measures to Minimize Risks
Receipt of Lead Agency Letter and copies of informed consent mailed to PI.	Some subjects will be contacted because they have abnormal mammography results.	The interviewers are trained to provide guidance on this issue, and will provide a list of resources to the subjects at the end of interview. The subject may skip a question if she is uncomfortable in answering.
Face-to-face interview with the PI or the consultant to complete a survey instrument/telephone interview. Interviews will be audio taped.	Breach of confidentiality	The audiotapes will be erased or destroyed after the study is completed.
Medical Record Review	Breach of confidentiality	The investigators will not review the medical records. The nurse at the clinic will review the medical records. Stated in the consent form.

14. Benefits to Subjects. There is no direct benefit to the subject for participating in the study. The investigators will supply sources of referral to the subjects if needed.

15. PI responses to recommendations from 19 June 2002 MFR.

a. With regard to the protocol.

(1) Provide a letter of collaboration from each of the local health agencies that will provide support for subject recruitment for this study. **The PI is in the process of obtaining letters of collaboration from the four local health agencies. Letters of collaboration have not been provided yet.**

(2) On page 6 of the protocol it is stated that, all data collected and entered for analysis from the interviews will be anonymous. Because there will be face-to-face interview with the subject, the data cannot be anonymous. Revise the statement to state that the data will be coded with unique identification codes. **The statement was revised to read, "All data collected and entered for analysis from the interviews will be coded using unique identification codes in order to protect confidentiality and will contain only the woman's age, and race, and other demographic information collected at the end of the interview.**

(3) In section Subject Identification, it is stated that, the log will be maintained until the end of the funding period and then destroyed. According to the regulations research records are to be maintained for a minimum of two years after the completion of the study. The records should be made available for auditing by the appropriate authorities during this period. Please revise the statement accordingly. **The statement has been revised to state that the log will be maintained in a locked file for a minimum of two years after completion of the study.**

(4) On page 1 of the PI's curriculum vita, in section Technical Experience, if the reference made to the subject protocol refers to the current protocol under review by the USAMRMC, update the resume to reflect that the focus of the study population is minority women. **The PI's CV was revised to reflect that the focus of the study population is minority women.**

b. With regard to the consent form.

(1) It should be specifically stated in the consent form that, "Other than medical care that may be provided and any other payment specifically stated in the consent form, there is no other compensation available for your participation in this research." **The statement was incorporated into the consent form. See section Compensation for Participation.**

(2) In the Roles and Responsibilities section, it is noted that the Graduate student/research assistant will be present during the face-to-face interview with the subject. This information was not included in the consent form. Provide the rational for having 2 persons performing the interview in the consent form. **The PI clarified in the consent form that the second person will help take detailed notes, and help answer any questions that the subject might have.**

(3) For participants who may be visually challenged, reading the fine print of the consent document may be difficult. Consider increasing the font to 12-point. **Done.**

c. With regard to the questionnaire.

(1) Provide a space to record the signature of the person conducting the interview. **Provided. See page 1 of the interview questionnaire.**

16. Points of Consideration

(1) In section Data Analysis Plan, further clarify the data analysis plan. Consider describing how you will code the data and validate the coding system. What will you consider to be the unit of analysis? Consider setting up a dummy table. **The PI has clarified that one person will be responsible for coding the responses and the other will be responsible for checking the codes against their own results in order to determine reliability of finding. A dummy table was incorporated into the Data Analysis Plan section.**

16. Recommendations for approval. The investigator has addressed all recommendations in the 30 April 2002, and the 19 June 2002 MFRs. The only outstanding issue is the submission of letters of collaboration from the 4 local health agencies that will provide support for subject recruitment for this study. Recommend that the PI submit the most current copies of the protocol, consent form and all the supporting documents to the local IRB for review and final approval. Approval from this office must be issued only upon receipt of the letters of collaboration from the 4 local health agencies, and submission of a final letter of approval from the local IRB.

MERCY P.SWATSON, RN, MSN
Human Subjects Protection Scientist
AMDEX Corporation

APPENDIX D

**North Carolina State University
Institutional Review Board for the Use of Human Subjects in Research
SUBMISSION FOR NEW STUDIES**

Title of Project: Increasing Follow-up Rates among Minority Women with Abnormal Mammography Results or Delays in Re-Screening

Principal Investigator Debra J. Holden, Ph.D.

Department Psychology

Source of Funding (**required** information): Department of Defense Concept Award (BC 995929)
(if externally funded include sponsor name and university account number)

Campus Address (Box Number) 7801

Email: debra_holden@ncsu.edu

Phone: 919/662-3896

Fax: 919/662-8250

RANK: Faculty
 Student: Undergraduate; Masters; or PhD
 Other (specify): _____

If rank is **other** than faculty, name of faculty sponsor overseeing the research: _____

Faculty Sponsor's Email _____ Campus Box _____ Phone _____

As the principal investigator, my signature testifies that I have read and understood the University Policy and Procedures for the Use of Human Subjects in Research. I assure the Committee that all procedures performed under this project will be conducted exactly as outlined in the Proposal Narrative and that any modification to this protocol will be submitted to the Committee in the form of an amendment for its approval prior to implementation.

Principal Investigator:

Debra J. Holden, Ph.D.

(typed/printed name)

(signature)

(date)

As the faculty sponsor, my signature testifies that I have reviewed this application thoroughly and will oversee the research in its entirety. I hereby acknowledge my role as the principal investigator of record.

Faculty Sponsor:

(typed/printed name)

(signature)

(date)

PLEASE COMPLETE IN DUPLICATE AND DELIVER TO:

Institutional Review Board, Box 7514, NCSU Campus (Leazer Hall Lower Level)

For IRB office use only

IRB Committee Reviewer

Approve Approve pending modifications Table Disapprove

Reviewer Name: _____ Signature: _____ Date: _____

Final IRB Committee Decision

Exempt Review Expedited Review Full Review Not Approved

Committee Chairperson

Date

RECEIVED: _____ SENT TO REVIEWER: _____ LETTER TO PI: _____

North Carolina State University
Institutional Review Board for the Use of Human Subjects in Research
PRELIMINARY QUESTIONS

- 1) Is this a taste and food quality evaluation and consumer acceptance study, where (i) wholesome foods without additives are consumed or (ii) food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture ?
 Yes No
- 2) Will the subjects remain completely anonymous (i.e. no identifiers which can link an individual subject to their data – projects using coded data sheets with a “key” linking code numbers to subjects are not anonymous)?
 Yes No
- 3) Will anyone other than the PI or the research team have access to the data (including any completed surveys) from the moment they are collected until they are destroyed?
 Yes No
- 4) Is your subject population going to consist of only elected or appointed public officials?
 Yes No
- 5) Does your research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior?
 Yes No
- 6) Does your research involve the analysis of existing data, documents, records, pathological specimens or diagnostic specimens?
 Yes No
- 7) In your estimation does the study involve no more than minimal risk to the subjects (see definition of minimal risk in the Policies and Procedures page)
 Yes No

North Carolina State University
Institutional Review Board for the Use of Human Subjects in Research
GUIDELINES FOR A PROPOSAL NARRATIVE

In your narrative, address each of the topics outlined below. Failure to follow these directions will result in delays in reviewing/processing the protocol.

A. INTRODUCTION

1. Briefly describe in lay language the purpose of the proposed research and why it is important.
To better understand why minority women are much less likely to follow-thru with recommendations to obtain mammography re-screening in a timely manner or to receive an abnormal mammography result and use the input of women from this target group to design an initiative to address this disparity.

2. If student research, indicate whether for a course, thesis, dissertation, or independent research.

N/A

B. SUBJECT POPULATION

1. How many subjects will be involved in the research? 60
2. Describe how subjects will be recruited. Nursing staff of local agencies that have contracted with the North Carolina Breast and Cervical Cancer Early Detection Program (NCBCCEDP) will review medical charts of women screened by this Program within the past 3 years. Their review will start from a list of women provided by the State Health Department directly to the Local of women who have either obtained mammogram screening as recommended for at least 2 of the past 3 years or women who have not returned for re-screening or follow-up at anytime during the past 3 years. The nurse at each local agency (typically a local health department or community health center) will then mail the women two copies of the consent form (Appendix A), with a letter from the health department explaining the reason for contacting her (Appendix B), and a stamped, self-addressed envelope for the woman to return her signed consent form to the researcher. The woman will sign one consent form and return it by mail for contact by the researchers in scheduling a face-to-face interview. Recruitment efforts will continue until approximately 60 minority women (30 who have received screening as recommended, and 30 who have either not received re-screening or diagnostic care as recommended) are located that meet the study criteria and agree to participate in the study.
3. If applicable, please provide the IRB office with a copy of any advertisement to be used in recruiting subjects. This includes print ads as well as scripts for radio and television ads. If this is not applicable, please check here
4. List specific eligibility requirements for subjects (or describe screening procedures), including those criteria that would exclude otherwise acceptable subjects.
Minority women, ages 50 years or older, receiving a mammogram through any of 3-4 of these local NCBCCEDP agencies during the past 3 years (1999-2001) will be possible study participants. The focus of the study will be on two groups of women: those who have obtained a mammogram at least 2 of the past 3 years, as recommended for their age group and those who have not obtained a mammogram all 3 years, or have not returned to receive diagnostic care after receiving an abnormal mammogram result. Using a list of participant identifiers supplied directly from the State Health Department, local agency staff will verify that women meet one of these two criteria and mail the study's consent form to the woman.

with the lead letter on agency letterhead, requesting she return it to the researchers.
Women who are not representatives of a minority population (African American, Native American, Hispanic, or Asian) will not be included since they are more likely to obtain re-screening or diagnostic care as recommended.

5. Explain any sampling procedure that might exclude specific populations (women, minorities, elderly).
No special populations will be excluded other than those identified above.
6. Disclose any relationship between researcher and subjects - such as, teacher/student; employer/employee.
None.
7. Check any vulnerable populations included in study:
 minors (under age 18) - if so, have you included a line on the consent form for the parent/guardian signature
 fetuses
 pregnant women
 persons with mental, psychiatric or emotional disabilities
 persons with physical disabilities
 economically or educationally disadvantaged
 prisoners
 elderly
 students from a class taught by principal investigator
 other vulnerable population.

If any of the above are used, state the necessity for doing so. Please indicate the approximate age range of the minors to be involved. Women who have obtained screening through their local health department will be included in this study. Since many are provided low cost or free mammograms because of their low income (they must be 200% of poverty level or below to qualify), nearly all of the respondents are expected to be from low income areas. In addition, only women 40 years of age or older are recommended for regular women and the program collaborating on this project, the North Carolina Breast and Cervical Cancer Control Program, focuses on providing screening to women 50 years of age or older. Therefore, some of the respondents in this study will likely be 65 years of age or older.

C. PROCEDURES TO BE FOLLOWED

1. In lay language, describe completely all procedures to be followed during the course of the experimentation. Provide sufficient detail so that the Committee is able to assess potential risks to human subjects. State-based epidemiological data will be used to identify 3-4 counties within North Carolina that have had a high rate of late-stage diagnosis of breast cancer among minority women. Women who have obtained either screening or follow-up later on in their disease progression are more likely to have their cancer identified at a late stage. Studies have shown that a disproportionate number of these women are African American, or from other minority groups. Through collaboration with the State Health Department, the local public health agencies in these selected areas of high need will be contacted. Once the agency agrees to participate in the study, they will be provided with consent forms (Appendix A) to mail to women who qualify for inclusion in the study. Study selection criteria will be

explained to the agency staff, including 1) women representing a minority population; AND 2) women who have obtained re-screening mammograms as recommended for at least 2 of the past 3 years OR have NOT obtained re-screening and/or diagnostic care as recommended within the past 3 years or as a result of the current screening visit. Once these women are identified by the local agency, their staff will mail the consent form to obtain each woman's permission to provide the researchers with her name and contact information (Appendix A). Two copies of the consent form will be mailed by the local agency to the woman and accompanied by a lead letter on agency letterhead (Appendix B) and a stamped, self-addressed envelope for returning a signed consent directly to the researcher. The women will be directed to keep a copy of the consent form for herself. Each consenting woman will then be contacted by phone to schedule a face-to-face interview at her convenience. The target for the study is to complete 30 interviews with women who have received screening as recommended and with 30 women who have not. Participation will be completely voluntary and confidential and it will be explained to her that her involvement(or not) will not impact any future care provided by the local agency. Once they agree to be interviewed, the researcher will arrange for a 1-hour face-to-face interview to be conducted at a conveniently located public building in her area, such as a library, the health department, or a senior health center. Each of the women completing at least half of the interview will receive a \$50 cash reimbursement. Part of the \$50 incentive can be used by the woman to cover her transportation costs to the interview site. Attempts will be made to obtain a private setting for the interview so that confidentiality is maintained. For women who are not able to travel to a convenient location (such as she is disabled or has limited access to transportation), but she consents to participate in the study, she will be provided the option of completing the interview over the phone. This option will be provided only as a last resort to obtaining information from women who might otherwise drop out of the study. Face-to-face interviews for this study are considered to be the best methodology, but telephone interviews could be substituted if necessary. The purpose of the interview will be to talk to the women about their understanding of the results they received, what they have done to obtain care since receiving their abnormal results, barriers they had to overcome to obtain any care that they have, or reasons she has or has not obtained care (Appendix C). The notes from this interview will be written by the interviewer and audio recorded. However, they will not include the woman's name or identifiers and will be completely anonymous once the interview is over. In other words, even though the interviewer will meet the woman, all of the notes from the interviewers will be compiled for final analysis, with no identifiers for individual women. The contact information is used strictly to locate the women and invite their participation and will then be destroyed.

2. What will subjects be asked to do? Participate in a face-to-face interview to discuss her understanding of the abnormal results or the need for re-screening and her rationale for the health practices she has followed.
3. How much time will be required of each subject? One hour interviews. For their time and input, the women will be provided a \$50 reimbursement for participating in the interviews. Women who complete at least 1/2 of the interview but refuse to answer some of the questions will still be provided the \$50 incentive.

D. POTENTIAL RISKS

1. State the potential risks (physical, psychological, financial, social, legal or other) connected with the proposed procedures and explain the steps taken to minimize these risks.
The only risk is that a few of the women will be contacted because they have received abnormal mammography results. The interviewers are highly trained on this issue and the woman will be allowed to skip or refuse to answer questions that make her feel uncomfortable.

2. Will there be a request for information which subjects might consider to be personal or sensitive (e.g. private behavior, economic status, sexual issues, religious beliefs, or other matters that if made public might impair their self-esteem or reputation or could reasonably place the subjects at risk of criminal or civil liability)? If yes, please describe and explain the steps taken to minimize these risks.

Yes. It is potentially sensitive information that a woman asked to participate in this has received an abnormal mammography result. However, the researchers will not know her results and during the interview, will ask what her results were and what her understanding of the follow-up care is that she needs to obtain because of these results. The interviewers are highly trained to be sensitive to the needs of the respondent, not be judgmental of her actions, and not provide medical advice under any circumstances.

3. Could any of the study procedures be considered as offensive, threatening, degrading, or could study procedures produce stress or anxiety? If yes, please describe why they are important and what arrangements have been made for psychological counseling.

It is possible that by participating in the face-to-face interview a woman will be more willing to face the consequences of an abnormal result. It is possible that some of the women will have been in denial about the need for follow-up and that, just by talking about this issue, will be more likely to face it and realize the potential risk to their health from these results. Both lead interviewers have extensive psychological or social work counseling experience and will conclude each interview with questions about how the women feel about their interview. The researchers will inform the women that they can return to the local health department for more specific information on next steps to take and will be provided with a sheet listing resources in their area for discussing this issue.

4. Describe methods for preserving confidentiality. How will data be recorded and stored? How will identifiers be used? How will reports will be written, in aggregate terms, or will individual responses be described?

Reports will only be written in aggregate form, analyzing data with no personal identifiers.

5. If audio or videotaping is done how will the tapes be stored and how/when will the tapes be destroyed at the conclusion of the study.

All interviews will be audio recorded. All recordings will be kept in a locked file until they are transcribed. Once they are transcribed and checked for errors, they will be erased.

6. Is there any deception of the human subjects involved in this study? If yes, please describe why it is necessary and describe the debriefing procedures that have been arranged.

No.

E. POTENTIAL BENEFITS

Please address benefits expected from the research (this does not include compensation for participation, in any form). Specifically, what, if any, direct benefit is to be gained by the subject? If no direct benefit is expected, but indirect benefit may be expected (knowledge may be gained that could help others), please explain.

The primary purpose of this study is to understand the reasons for this life-threatening disparity so that an initiative can be developed to address the problems identified. It is a demonstration project to obtain information from the women most at risk for not following thru with medical recommendations.

F. COMPENSATION

1. Explain compensation provisions if the subject withdraws prior to completion of the study.

Consent to participate in the interviews will be obtained through the mail and a convenient interview time and location scheduled. It will be explained that when a woman completes at least 1/2 the interview, she will receive \$50 cash payment.

Reimbursement will not be provided to a woman if she withdraws prior to completing at least 1/2 the interview. For example, if a woman is attempting to answer at least half

of the questions but requests to skip some of them, she will still be provided with this reimbursement. This will be explained to all participants prior to starting the interview.

2. If class credit will be given, list the amount and alternative ways to earn the same amount of credit.

N/A

G COLLABORATORS

If you anticipate that additional investigators (other than those named on Cover Page) may be involved in this research, list them here indicating their institution, department and phone number.

Rebecca D. Martin, Ph.D., Independent Consultant, 919/541-7403; Autumn Cano, Graduate Research Assistant, Psychology Department, Boc 7801, 919/515-1755; and Amy Ladner, MPH, Independent Consultant, 919/541-6491.

H. ADDITIONAL INFORMATION

1. If a questionnaire, survey or interview instrument is to be used, attach a copy to this proposal.
 2. Attach to this proposal a copy of the informed consent document that you will use.
 3. Please provide any additional materials or information that may aid the IRB in making its decision.
-

APPENDIX E

NC STATE UNIVERSITY

Sponsored Programs and
Regulatory Compliance
Campus Box 7514
1 Leazar Hall
Raleigh, NC 27695-7514

919.515.7200
919.515.7721 (fax)

From: Debra A. Paxton, IRB Administrator
North Carolina State University
Institutional Review Board

Date: March 14, 2002

Project Title: Increasing Follow-up Rates among Minority Women with Abnormal Mammography
Results of Delays in Re-Screening

IRB#: 0047-02-3

Dear Dr. Holden:

The project listed above has been reviewed in accordance with expedited review procedures under Addendum 46 FR8392 of 45 CFR 46 and is approved for one year. **This protocol expires on March 7 2003, and will need continuing review before that date.**

NOTE:

1. This board complies with requirements found in Title 45 part 46 of The Code of Federal Regulations. For NCSU the Assurance Number is: M1263; the IRB Number is: 01XM.
2. The IRB must be notified of any changes that are made to this study.
3. Your approval for this study lasts for one year from the review date. If your study extends beyond that time, including data analysis, you must obtain continuing review from the IRB.

Thank you.

Sincerely,

Debra Paxton
NCSU IRB

APPENDIX F

SUMMARY OF THE STUDY ON INCREASING RESCREENING AND FOLLOW-UP RATES AMONG MINORITY WOMEN

Study Goals:

Immediate

- To interview 30 minority women, aged 50 years or older, in 3-4 North Carolina counties who have received mammography re-screening as recommended for at least two of the past three years; and,
- To interview 30 minority women, aged 50 years or older, in 3-4 North Carolina counties, who have not received the recommended mammography re-screening (e.g., have missed at two of the last three years) or follow-up care during any of the past 3 years.

Intermediate

- To develop, in conjunction with NCBCCCP, an innovative, community-based intervention to overcome identified problems and barriers to breast cancer re-screening and follow-up.

Ultimate

- To improve the rates of re-screening and follow-up for breast cancer among minority women by better understanding the variables that predict these behaviors.

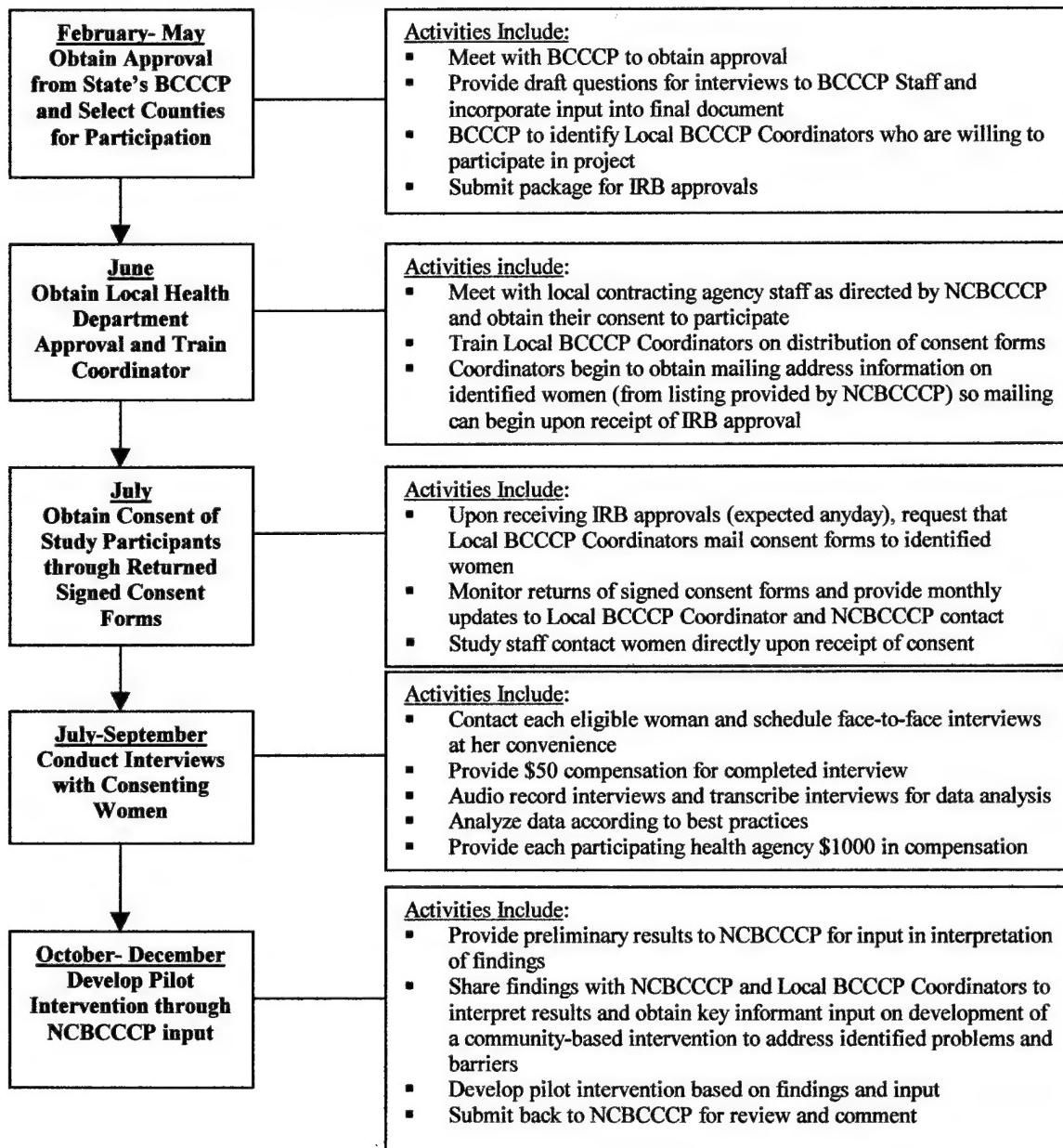
Study Procedures

1. As specified in the Flow Chart (*page 2*), the study will be conducted with ongoing NCBCCCP involvement and feedback.
2. Once appropriate approvals are obtained, the study questions to respondents will be finalized with NCBCCCP input and an IRB package submitted for approval.
3. While waiting on IRB approval, NCBCCCP will provide guidance on the selection of 3-4 local agencies contracting to provide services for NCBCCCP for participation in the study, based on analyses of data for minority women screened within the past 3 years (calendar years 1999, 2000, and 2001).
4. Each of these Coordinators of the chosen agency will be contacted and a face-to-face meeting scheduled with the Study Leaders (Drs. Holden and Martin) at the agency. Funding will be established so that each Local BCCCP Clinic will receive \$1000 as compensation for participating. This compensation will be provided to NCBCCCP directly and local participating clinics will be provided a product catalog to choose items to help in the delivery of services (i.e., breast models, educational materials, etc.). Each local clinic will be allowed to order items equal to their level of compensation for assisting in the study.
5. During the meeting in the local agency's office, the purpose of the study will be explained, along with the selection criteria for women who can participate. A listing of the qualifying women will be provided directly from NCBCCCP to the Local BCCCP Coordinator for mailing out consent forms. The consent form, accompanied by a lead letter from the local contracting agency (complete packages will be provided by the Study Staff to the local agency directly), will be mailed by the Local BCCCP Coordinator to each qualifying woman. Signed consent forms will be returned directly to the Study Staff and copies provided to the Local contracting agencies for their records (*if requested*).
6. Once a woman consents to be involved, the Study Staff will contact her directly to arrange for a face-to-face interview. All women who complete at least half of the interview will be provided with \$50. Women will be allowed to skip or refuse questions and still receive

compensation. Telephone interviews may be completed with some women who have limited transportation or are home bound.

7. Findings of this study will be provided to NCBCCCP for review and input into the interpretation of results, as well as for planning for development of an intervention to address the identified concerns and problems.

Flow Chart of Activities for Completing Proposed Study



APPENDIX G

Department of Defense Study Entitled:
"Increasing Follow-up Rates Among Minority Women with Abnormal Mammography Results or Delays in Re-Screening"

Prior to interview, record the following information for each interview:

Date of interview _____
ID code of subject _____
Name of person conducting interview _____
Signature of person conducting interview _____

Script and Questions for Face-To-Face Interviews

Hello, my name is _____. I wanted to come meet with you today to talk about your experiences in obtaining care for a mammogram that you received from the _____. BCCEDP contracting agency on _____. A couple of weeks ago, I called and scheduled this meeting with you to talk about this experience.

RE-READ components of consent related to confidentiality, use of information, and purpose of research.

Section I

To get started, I'd like to ask you a few questions about your general health care.

1. Do you have a doctor or nurse that you see on a regular basis?

Yes

No
2. When did you last see a doctor or nurse for your breast health?

Within the past year

1-2 years ago

More than 2 years ago
3. What was the reason for this last visit?
4. Where was this doctor or nurse located?

In a private practice

In a hospital setting

In the local BCCEDP contracting agency →
(if this is the response, skip to Item 6)

Some other place, please specify _____
5. When was the last time you went to the _____ BCCEDP contracting agency for your breast health?

Have not returned since receiving the mammogram

- Within the past year
 1-2 years ago
 More than 2 years ago

If she has not returned to the BCCEDP contracting agency:
Do you plan to ever return for breast health care at your local BCCEDP contracting agency? Why or why not?

6. Would you say you've been very satisfied, somewhat satisfied, or not at all satisfied with the breast health care you received at your local BCCEDP contracting agency during your last visit?

- Very satisfied
 Somewhat satisfied
 Not at all satisfied

What are the reasons for the response you just gave?

7. How did you know you could get a mammogram through your local BCCEDP agency?
8. Have family members or friends of yours received a mammogram through this (or another) local BCCEDP contracting agency?
9. What was your primary reason for getting a mammogram at the _____ BCCEDP contracting agency?
10. The mammogram you received then was provided through a state program called the Breast and Cervical Cancer Early Detection Program. Have you ever heard of this program?

- Yes
 No

If yes, how did you hear about it?

Section II

Now I'd like to ask you some more specific questions about any care you've received for your breast health.

1. A clinical breast examination is when a doctor or nurse examines the breast for lumps. When did you have your most recent clinical breast examination?
2. Has your doctor or nurse ever told you that you had a lump in your breast?

- Yes
 No

If yes, when was this? Date or year lump was found _____

Did he or she ask you to complete any tests to find out what it was?

_____ Yes
_____ No

If yes, what was the result of these test(s)?

3. Do you currently have any breast problems, such as lumps, unusual pain, soreness, or discharge?

_____ Yes
_____ No

If yes, do you know what is causing this breast problem?

_____ Yes
_____ No

Have you told your doctor or nurse about this problem?

_____ Yes
_____ No

If yes, what did s/he tell you to do about it?

If no, do you plan to talk about it with your doctor or nurse during your next visit? (if yes, when do you plan to go the next time?)

Section III

As you remember, you had a mammogram through the _____ BCCEDP contracting agency at sometime during the past three years. The following questions are about mammograms and any additional tests you've received since then.

1. When did you receive your last mammogram?
2. Who referred you for your last mammogram? (Probe: who told you to go get your last mammogram?)
_____ your local doctor or nurse
_____ your local BCCEDP contracting agency
_____ a doctor or nurse at another facility (*if so, where?*)

[*If not at the local BCCEDP contracting agency*] what were your reasons for not getting another mammogram at your local BCCEDP contracting agency?

3. What do you remember was the result of that last mammogram?

Carefully follow these criteria for determining next set of questions:

If she has received a mammogram within the past year AND her results were 'normal', go to Item C on page 5

If she has NOT received a mammogram within the past year but the last one was 'normal', go to Item A below.

If she has NOT received a mammogram within the past year, but the last one was 'positive' or 'abnormal', go to Item B below.

A. For those needing re-screening:

What are your primary reasons for not returning to get another mammogram within a year after your last one?

Has a doctor or nurse ever told you that you should receive a mammogram at least once a year?

Yes
 No

If yes, when was the last time you were told this?

Do you agree with what they said? If not, what are your reasons for disagreeing?

Do you plan to get another mammogram?

Yes
 No

If yes, when do you think you will get another mammogram?

Within the next 6 months
 Within the next year (but more than 6 months from now)
 Within the next 2 years (but more than 1 year from now)
 More than 2 years from now

If 1 year or more from now before getting another mammogram, what are your primary reasons for not getting a mammogram within the next year?

For those completing Item A above (have not received mammogram in past year AND had normal results on last one), continue now to Section IV

B. For those needing diagnostic care:

What does that result mean to you?

What did your doctor or nurse tell you to do about it?

How did you feel about getting this result?

With this result, what did you think you should do about it, if anything?

You mentioned that for the results, the recommendations given to you by your doctor or nurse were (*from answer above*), did you obtain this care?

Yes
 No

If no, have you received any care from a doctor or nurse about this result?

Yes
 No

If yes to *any care*, when did you receive this care? Date or Years since care received _____

What was the care you received? (Probes: do you remember the names of any other breast tests you received? What were the results of these tests?)

If no to *any care*, what are your primary reasons for not receiving any more care for this mammogram result? What do you think will happen to you since you haven't received any care?

For those completing Item B above (received 'abnormal' results on last mammogram), continue now with Section IV

C. For those who have received screenings as recommended

How often do you typically receive mammograms? (*every year, every other year, etc.*)

What are your reasons for getting a mammogram on this schedule?

How important is it to you to get mammograms on a regular basis? What are the main reasons this is important to you?

What barriers have you ever experienced in getting a mammogram on a regular (or yearly) basis?

Section IV

Now I would like to ask you some questions about your impressions and opinions on things related to getting regular breast health care. Please feel free to be open and honest with your responses and let me know what you really think.

1. Tell me about your overall experiences in getting mammograms. What would you say was positive about your experience of getting this test? What was negative about this experience?

2. When you think about scheduling an appointment for getting a mammogram, what are some reasons that you think about for postponing getting one or deciding not to get one? What are some reasons for not putting it off?

3. How often do you think you need to receive a mammogram?

4. Do you think women 50 years or older should get mammograms every year?
____ Yes
____ No

5. What does the word 'cancer' mean to you? (Probe: tell me what you think of when you hear the word 'cancer')

6. What kind of treatment do you think that a woman would have to have if she found out she had breast cancer? (Probe: Do you think that every woman who has breast cancer has to have one or more breasts removed?)

7. What do you think makes a woman your age more likely to have breast cancer? (Probe: Do you think that a woman who's relatives have had breast cancer will probably get it too? What do you think are the characteristics of women who are most likely to have breast cancer?)

8. How likely do you think it is that a woman diagnosed with breast cancer will survive and live a good life for at least 10 more years?

9. Would you say your family is supportive of you getting regular check-ups for your breast health?
____ Yes
____ No

What do members of your family say or do to let you know they support you getting this care?

What do members of your family say or do to discourage you from getting this care?

10. Would you say that all, almost all, a few, or none of your closest friends get regular mammograms (that is, at least once a year if they're over 50 years of age)?
____ All
____ Almost all

A few
 None

What do your closest friends say or do to let you know they support you getting this care?

What do your closest friends say or do to discourage you from getting this care?

11. Do you know anyone who has ever been diagnosed with breast cancer? What is your relationship to this person? What happened to them? Do you think their experience has influenced what you have done with regards to receiving care for breast health? If yes, in what ways?

Section V

I just have a few more questions to ask about your background. We should be finished in about 5 minutes and I appreciate your help with this study.

1. What is your date of birth?
2. What is the total number of years of schooling you have completed?
3. Has any of your immediate family (including grandparents, parents, and siblings) been diagnosed with cancer? If yes, what is their relationship to you?
4. What is your primary occupation? If retired, what job or occupation did you work in the most during your working years?

If currently working, does your work place allow for you to have time off to obtain screening, like mammograms, in order to maintain good health?

6. What is your current marital status?

Thank you so much for your help in answering these questions. The information you provided will be used to develop a program that better meets the needs of women in getting regular and timely breast health care. Should you think of anything else you would like to share with me, please feel free to contact me (give respondent contact information and provide with \$50 incentive before leaving).

APPENDIX H

EXECUTIVE SUMMARY

INCREASING RESCREENING AND FOLLOW-UP RATES AMONG MINORITY WOMEN IN NORTH CAROLINA

Although a higher proportion of black women than white women of all ages have reported being screened for breast cancer, mortality rates for black women are higher than those for white women. Even though the proportion of black and white women with invasive disease upon diagnosis is similar, African American women are more likely to die from the disease. Differences in follow-up and treatment are two of many reasons for this disparity. The proportion of mammograms interpreted as abnormal in large screening programs is as high as 15-20%. Thus, if 15% of the 48 million American women 40 years of age or older have mammograms, there would be more than 7 million abnormal mammography results each year. It has been estimated that 30% or more of women with abnormal mammograms fail to comply with follow-up recommendations. It is also the case that many minority women who obtain one mammogram are also more likely than white women to not obtain re-screening as recommended. This proportion is disparate across racial groups, such that women from minority populations are less likely to receive follow-up than white women. There is little known about why this disparity exists and a need to find out more in order to decrease the number of black women dying from this disease. This study proposes to look at this existing problem from a new perspective— that of the minority woman. The goal of this study is to improve the rates of follow-up in minority women after an abnormal mammogram result and to improve re-screening rates by understanding the variables that predict follow-up and developing an innovative intervention through community input that overcomes obstacles to follow-up.

Study Goals:

Immediate

- To interview 30 minority women, aged 50 years or older, in 3-4 North Carolina counties who have received mammography re-screening as recommended for at least two of the past three years; and,
- To interview 30 minority women, aged 50 years or older, in 3-4 North Carolina counties, who have not received the recommended mammography re-screening (e.g., have missed at two of the last three years) or follow-up care during any of the past 3 years.

Intermediate

- To develop, in conjunction with the North Carolina Breast and Cervical Early Detection Program (NCBCCEDP), an innovative, community-based intervention to overcome identified problems and barriers to breast cancer re-screening and follow-up.

feedback both to the State and Local Health Departments. These questions focused on the women's reasons for obtaining care at the LHD, whether they had returned for care, and their level of satisfaction they reported during their visit.

Overall, women reported being very satisfied with the breast health care they had received through their local BCCEPD program. Nearly all of the women reported being very satisfied with their care, while 5 (12.8%) stated they were somewhat satisfied. The reason reported by the most women for being so pleased with the care they received was that the care was thorough and the nurse explained things well (19: 48.7%). Another primary reason for the high level of satisfaction was that the women felt they had been treated with respect and courtesy (11: 28.2%). One woman even stated that the LHD is the only place she can go where she can count on "*...being treated like a person not like a number*".

Women were also asked how they came to know about obtaining breast health services at the LHD. Respondents provided a variety of answers to this question.

Advertisements through posters, letters, and in newspapers, were reported by 13 (33.3%) women as how they initially learned of these services. Referrals within the community also seemed to be an effective mechanism for outreach to qualifying women, with 10 (25.6%) reporting being referred by another clinic (either one within the LHD or at another local agency), 3 (7.7%) referred by attending a local community event, such as a workshop on breast health, and 2 (5.1%) referred by their private physician. Word of mouth was also responsible for 5 (12.8%) women hearing about the program through family members or friends.

Conclusions

Overall, the findings of this study indicate that the women in this sample are relatively positive about the ongoing need for early detection of breast cancer and seem to understand the value of this behavior. Implications from this study include three strategies that could be utilized to provide outreach to more women for screening and re-screening and to help promote adequate follow-up care:

- 1. Utilizing breast cancer survivors more in delivering messages of the importance of early detection.** Many women acknowledged that they knew some survivors of cancer, but few were breast cancer survivors. The women also overwhelmingly expressed great fear and anxiety over the potential for a diagnosis of cancer. While much of this fear is real, it could be alleviated by introducing women to those who have survived the disease so that they understand that it is quite likely that, if found, a woman can survive diagnosis, and that cancer does not necessarily mean death, like many women seemed to believe.

Ultimate

- To improve the rates of re-screening and follow-up for breast cancer among minority women by better understanding the variables that predict these behaviors.

Study Procedures

Face-to-face or telephone interviews were conducted among women residing in one of three North Carolina counties, including Cabarrus, Randolph, and Robeson. The focus of the interview asked women about their health behaviors, particularly those related to breast health. Through guidance from the North Carolina Department of Health and Human Services (NCDHHS), the Local Health Departments (LHD) in each of these three counties were selected for participation because their local population includes a great deal of racial/ethnic diversity, and they had demonstrated some difficulty in providing re-screenings to more than half of their eligible women. Local visits were made to each LHD to explain the study and enlist their support. The NCDHHS provided each participating LHD with a list of eligible women from the NCBCCEDP as derived from the Minimum Data Elements (MDE) reported by each LHD. Each LHD was provided with prepared packages to mail to eligible women for invitation into the study and received \$1000 compensation for their assistance in conducting this study. Each participating women was compensated \$50 for her time in completing an interview. An interview guide was developed and reviewed by the NCDHHS prior to study implementation. Quantitative and qualitative data were analyzed according to standard procedures and summarized in a final report to the funding agency, the Department of Defense (DoD).

Overview of Results

A total of 39 women (21.7% of those mailed a package) agreed to participate in the study and completed a telephone or face-to- face interview. Study participants ranged in age from 51- 68 years, with a median of 56 and a mean of 59.5 years. More than half of the participants were African American (24: 61.6%), while 8 (20.5%) were White and 7 (17.9%) were Native American. Nearly half of the women (46.1%) did not complete high school, with the mean years of education of 11.3. The majority of these women had been obtaining annual mammograms (32: 82.1%), with only 7 (17.9%) reporting no mammograms within the twelve months prior to the interview. Barriers to screening included lack of time to schedule and/or keep an appointment, inability to get off work to keep an appointment, or other health issues.

Of key interest to the NCDHHS was the level of satisfaction among women about their encounter at their LHD and reported reasons that they may not return for care. Questions related to this were added into the interview guide in order to provide

- 2. Delivering breast health care messages through the adult children of older women.** Interestingly, several women noted that they are encouraged or reminded by friends and family members to obtain regular screening. In addition, a number of women noted that they get this support from their adult children. A viable strategy would be to provide for education of adult children so that they can promote ongoing screening behavior with their parents. Strategies could be developed to enlist their ongoing support and enhance their understanding of the importance of early detection.
- 3. Increase awareness of the ongoing availability of NCBCCEDP funding and the need to continue receiving services.** Many of the women knew about the NCBCCEDP and knew that this Program (or the LHD) had paid for at least one of their mammograms. However, several also seemed to indicate that they did not know they could continue to access this Program if they were financially eligible. Strategies could be used that would continuously inform women of the availability of this Program, so that they understand they can return for re-screening and receive the same kind of financial support that they did the last time they obtained a mammogram.

In applying these strategies, it is important to keep in mind the limitations of this study. In order to obtain both NCDHHS and DoD approval, a number of concessions had to be made that impacted the ability to reach the population of greatest interest. It was hoped that this study would reach primarily women of color who had either not obtained follow-up care as recommended or had not returned for re-screening mammograms. As evidenced by this sample, the majority of women included in this study did not meet these criteria. It could be that the women least likely to be obtaining regular screening and/or recommended diagnostic care are also among those least likely to participate in this type of study. However, the approved recruitment strategy for the study was problematic and included relying on LHD staff to invite women to the study who met the criteria and minimizing initial, direct contact with eligible women in order to explain the study and enlist their involvement. Through concessions made to receive approval to proceed, initial contact with the women was conducted through the LHD by mail (versus the phone) and this proved to be a fairly ineffective way to recruit women into a study of this nature. If this study were to be repeated, considerations should be made that would enhance participation in the study among women who are not receiving adequate screening and/or diagnostic breast health care.

APPENDIX I

Roles and Responsibilities of Study Personnel

Debra J. Holden, Ph.D.-- Principal Investigator

Obtain cooperation with all study partners, including the North Carolina Breast and Cervical Cancer Control Program and the local agencies selected to participate. Create research protocol and study questions. Train study staff on their roles and responsibilities and supervise all activities. Conduct ½ of study interviews and oversee data analysis and reporting. Oversee budget monitoring and overall conduct of study.

Rebecca D. Martin, Ph.D.-- Consultant

Assist in establishing collaborative relationship with all study partners, attend meetings to negotiate study protocol, and provide input into accomplishing study goals within the study's context. Provide guidance and input into IRB package, study protocols, consent forms, etc.

Autumn Cano Guin, MS-- Graduate Student Research Assistant

Conduct literature review to inform protocol development. Coordinate study activities including contacting consenting women to participate in the study (once consent is received via mail). Schedule interviews and coordinate sessions. Conduct telephone interviews and/or assist Dr. Holden in interview sessions by being present for note-taking and audio-taping interview.